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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

MAN-U SERVICE CONTRACT TRUST FUND,	:	
on behalf of itself and all others similarly	:	
situated,	:	
	:	Civil Action No.
Plaintiff,	:	
	:	
v.	:	
	:	CLASS ACTION
WYETH, INC.,	:	
	:	<u>JURY TRIAL DEMANDED</u>
Defendant.	:	

CLASS ACTION COMPLAINT

Plaintiff, Man-U Service Contract Trust Fund, on behalf of itself and the class of End-payors as defined below, upon personal knowledge as to facts pertaining to itself, and upon information and belief and upon the investigation of their counsel as to all other matters, alleges as follows:

NATURE OF THE ACTION

1. This is a nationwide class action alleging violations of federal antitrust law and state antitrust and unfair and deceptive trade practices acts arising from the manufacture and marketing by Wyeth, Inc. (“Wyeth”) of the brand-name drug Effexor XR, a drug used to treat depression. Effexor XR is an extended release form of the compound venlafaxine hydrochloride

(“venlafaxine”). Plaintiffs are consumers and third-party payors (such as insurers and employee benefit plans) who paid some or all of the price of Effexor XR or its generic version for use and not for resale.

2. As detailed below, Wyeth engineered a scheme to monopolize the U.S. market for pharmaceutical products with extended release venlafaxine as the active ingredient by substantially delaying the onset of generic competition for Effexor XR. Although Wyeth’s marketing exclusivity for the original compound patent for Effexor XR ended on June 13, 2008, the generic equivalents were precluded for two more years, until June 2010, and other generics remained foreclosed until June 2011. Wyeth’s scheme included: (a) fraudulently procuring three patents for extended release formulations of venlafaxine; (b) wrongfully listing those patents in the FDA Orange Book; and (c) engaging in a series of sham lawsuits to block and delay at least 13 generic companies from entering the market for extended release venlafaxine capsules.

3. Wyeth obtained three “method of use” patents: - that is, patents which claim exclusivity for a newly discovered use of a previously known product or substance. These three patents ostensibly extended Wyeth’s monopoly on extended release venlafaxine by nine years, until March 20, 2017. Wyeth obtained these patents by misrepresenting material information to the U.S. Patent and Trademark Office (“PTO”). Wyeth knew that should the patents be challenged in court by would-be competitors, there was no realistic chance the patents would be upheld because:

a. Wyeth fraudulently claimed that clinical data showed that Effexor XR reduced the incidence of nausea and vomiting associated with the older instant release version.

b. Wyeth fraudulently claimed that its purported discovery of an extended release version of Effexor was unexpected, despite knowing (i) an earlier Wyeth patent (the

Upton Patent described below) and a patent application by a Wyeth collaborator (the '589 PCT application described below) previously disclosed extended release versions of Effexor; and (ii) one skilled in the art would be aware of several methods for achieving extended or sustained release formulations.

4. Wyeth failed to disclose that its own Upton Patent disclosed extended release venlafaxine. Wyeth further failed to disclose that the original patent examiner had found its method of use claims unpatentable in light of the Upton patent, and that Wyeth had agreed with this rejection.

5. Wyeth used the fraudulently obtained patents to block generic versions of Effexor XR from the market by listing these patents in the Orange Book and promptly filing baseless patent infringement litigation against each and every generic manufacturer that tried to bring an extended release venlafaxine product to market, thereby triggering the automatic 30-month stay of FDA approval provided by the governing Hatch-Waxman Act. Wyeth asserted generic manufacturers were infringing its method of use patents in at least 13 lawsuits. The generic manufacturers all responded by pointing out that Wyeth's method of use patents were invalid and/or unenforceable.

6. Wyeth listed the patents and initiated the infringement suits despite knowing the method of use patents were fraudulently obtained, invalid, and/or unenforceable. Without the invalid and/or unenforceable patents, Wyeth could not have manipulated the Hatch- Waxman Act to exclude generic versions of Effexor XR, and generic manufacturers would have obtained FDA approval to sell their far less expensive extended release venlafaxine products at least two years earlier.

7. Wyeth settled each and every lawsuit before a court determined whether the three

methods of use patents were invalid and/or unenforceable. The settlements preserved Wyeth's market exclusivity far beyond its lawful protection of mid-2008, and enabled first generic filer Teva to maintain and extend its generic exclusivity rights, while also providing Teva with significant additional benefits in exchange for its agreement not to market a generic version of Effexor XR until June 2010.

8. If Wyeth had not fraudulently obtained the method of use patents, had not listed those patents in the Orange Book, and/or had not brought sham infringement actions, generic extended release products would have launched for sale in June of 2008. Absent its fraud and other wrongful conduct, Wyeth could not have extended its monopoly in the market for extended release venlafaxine capsules beyond June 2008 through the settlements of its improper patent lawsuits - since those lawsuits would not have existed absent Wyeth's fraud in obtaining and/or listing the allegedly infringed patents.

9. As a result of Wyeth's fraud and other unlawful anticompetitive conduct, generic versions of Effexor XR were precluded from the marketplace from June 2008 through at least June 2010. During this period, U.S. retail sales of Effexor XR exceeded \$4.5 billion. End payors paid significantly more for extended release venlafaxine capsules during this period and continue to pay more for Effexor XR and its generic equivalents than they would have in the absence of Wyeth's illegal anticompetitive acts.

10. In Count I of this Complaint, Plaintiff, on behalf of itself and all others who are End-payors of Effexor XR, seek equitable, injunctive and declaratory relief against Defendant based on allegations of monopolization of, and an attempt to monopolize, the market for Effexor XR and its generic bioequivalents, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

11. Counts II and III are brought by Plaintiff on behalf of itself and those Class

members who purchased or paid for Effexor XR and its generic bio-equivalents in Arizona, California, the District of Columbia, Florida, Hawaii, Iowa, Kansas, Kentucky, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Mexico, New York, North Carolina, North Dakota, South Dakota, Tennessee, Utah, Vermont, West Virginia and Wisconsin (the “Indirect Purchaser States”). Counts II and III are brought pursuant to the antitrust and unfair and deceptive trade practices acts of the Indirect Purchaser States.

12. Count IV is brought by Plaintiff on its own behalf and on behalf of the Class, seeking a constructive trust and disgorgement of the unjust enrichment of Defendants.

JURISDICTION AND VENUE

13. This action is brought under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive and equitable relief to remedy Defendants’ violations of the federal antitrust laws, particularly Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2. The Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. § 26. In addition, this Court has jurisdiction over the state law claims pursuant to 28 U.S.C. § 1332(d), as amended in 2005, and 28 U.S.C. § 1367.

14. Venue is proper in this judicial district pursuant to 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) because Defendant has its principal place of business here, transacts business, is found, and/or has agents in this district; because a substantial portion of the affected trade and commerce described below has been carried out in this district; and because related cases were transferred here by the U.S. District Court for the Southern District of Mississippi and are now docketed here as *Professional Drug Co., Inc. v. Wyeth, Inc.*, C.A. No. 11-05479(JAP)(LHG).

15. The illegal monopolization and attempt to monopolize the market for Effexor XR and generic versions of Effexor XR, as alleged herein, have substantially affected interstate and

foreign commerce.

PARTIES

16. Plaintiff Man-U Service Contract Trust Fund (“the Man-U Fund” or “Plaintiff”)) is a trust fund established and maintained pursuant to Section 302(c)(5) of the Labor Management Relations Act, 29 U.S.C. § 186(c)(5), and is an employee benefit plan established and maintained pursuant to the Employee Retirement Income Security Act, 29 U.S.C. § 1001, *et seq.*, for the purpose of providing health benefits, including prescription drug coverage, to eligible participants and beneficiaries. The Man-U Fund maintains its principal place of business at 4600 Powder Mill Road, Suite 100, Beltsville, Maryland 20705. The Manu-U Fund provides comprehensive health coverage, including prescription drug coverage, for approximately 1,200 participants and beneficiaries located in Maryland, Delaware, Virginia, North Carolina, Pennsylvania and Washington, D.C. During the Class Period as described herein, Plaintiff has paid for some or all of the purchase price of Effexor XR prescribed to one or more of its participants or beneficiaries and has thereby been injured, and continues to be injured, as a result of Defendant’s conduct.

17. Defendant, Wyeth, Inc. (“Wyeth”) is a corporation organized and existing under the laws of the state of Delaware. Wyeth’s principal place of business is Five Giralda Farms, Madison, New Jersey 07940. Before 2002, Wyeth was known as “American Home Products.” As of October 2009, Wyeth is a wholly owned subsidiary of Pfizer.

18. Throughout this complaint, the phrase “Wyeth applicants” refers to Wyeth, the named inventors of the ‘171, ‘958, and ‘120 Patents, the prosecuting attorneys of the ‘171, ‘958, and ‘120 Patents, and agents thereof. The Wyeth applicants include, but are not limited to: inventors Deborah M. Sherman, John C. Clark, John U. Lamer, and Steven A. White and

attorneys Egon Berg, Ronald W. Alice, Arthur Seifert, Steven R. Eck, Robert Boswell Jr., and Rebecca Barrett. The term also includes any agents of these persons from Wyeth.

FACTUAL ALLEGATIONS

I. The Pharmaceutical Industry in the United States

A. Brand-Name Drugs vs. Generic Drugs

19. The manufacture, marketing, distribution and sale of prescription drugs is one of the most profitable industries in the United States. The U.S. market accounts for more than 40% of the world's prescription pharmaceutical revenues. The cost of prescription drugs in the United States has been rising at a rate of 14% to 18% per year, and the cost of drugs dispensed in the United States for the year 2001 was in the range of \$160 billion to \$170 billion.

20. The availability of generic drugs has been one of the most effective means of lowering the cost of prescription drugs. Generic drugs, which also must be approved by the FDA, have the same active chemical composition and provide the same therapeutic effects as the pioneer brand-name drugs upon which they are modeled. The FDA will assign an "AB" rating to generic drugs that are bioequivalent to pioneer or brand-name drugs.

21. To be deemed a therapeutical equivalent and assigned an "AB" rating by the FDA, the generic drug must contain the same active ingredient(s); dosage form and route of administration; and strength as the brand name drug. If so, the generic drug, as a therapeutical equivalent, can be substituted (and in some instances must be substituted) for the pioneer or brand-name drug at the pharmacy dispensing the drug.

22. Generic drugs are normally priced substantially below the brand-name drugs to which they are bioequivalent. A 1998 study conducted by the Congressional Budget Office (the "CBO") concluded that generic drugs save consumers and third-party payors between \$8 billion

and \$10 billion a year. A report prepared by the Government Accounting Office in August 2000 observed, “Because generic drugs are not patented and can be copied by different manufacturers, they often face intense competition, which usually results in much lower prices than brand-name drugs.”

23. The Federal Trade Commission (“FTC”) estimates that the first generic manufacturer to enter the market typically charges between 70% and 80% of the price of the brand-name drug. As additional manufacturers bring generic versions of the drug to market, the price continues to drop.

24. A brand-name drug loses a significant portion of its market share to generic competitors soon after the introduction of generic competition, even if the brand-name manufacturer lowers prices to meet competition. The 1998 CBO study estimates that generic drugs capture at least 44% of the brand-name drug’s market share in just the first year of sale.

B. The Federal Scheme For Approval Of Pioneer Drugs

25. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (the “Act”), approval by the FDA is required before a company may begin selling a new drug. Pre-market approval for a new drug, often referred to as a “pioneer” or “brand-name” drug, must be sought by filing a New Drug Application (“NDA”) with the FDA, demonstrating that the drug is safe and effective for its intended use. New drugs that are approved for sale in the United States by the FDA are typically (but not necessarily) covered by patents, which provide the patent owner with the exclusive right to sell that new or pioneer drug in the United States for the duration of the patents involved, plus any extension of the original patent period (the “FDA Exclusivity Period”) granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, 21 U.S.C. § 355 (“Hatch-Waxman Act”).

26. In addition to information on safety and efficacy, NDA applicants must submit to the FDA a list of all “prior art,” as well as patents that claim the drug for which FDA approval is being sought or that claim a method of using the drug and with respect to which a claim of patent infringement could reasonably be asserted. “Prior art” is the term used in patent law to refer to that body of previous knowledge and technology against which a patent application is judged to determine whether the claim is sufficiently novel to merit patent protection. When the NDA is approved, the FDA “shall publish” the patent information submitted by the NDA applicant. 21 U.S.C. § 355(b)(1).

27. Once the NDA is approved, the FDA lists any patents referenced as part of the NDA application process in a publication known as the *Approved Drug Products With Therapeutic Equivalence Evaluations*. This publication is commonly called the “Orange Book.” In listing patents in the Orange Book, the FDA merely performs a ministerial act. The FDA does not check the facts supplied to it by the brand name manufacturer, but trusts that the manufacturer will be truthful.

28. Once the safety and effectiveness of a new drug is approved by the FDA, it may be used in the United States only under the direction and care of a physician who writes a prescription, specifying the drug by name, which must be dispensed by a licensed pharmacist. The pharmacist must, in turn, fill the prescription with the drug brand specified by the physician, unless an AB-rated generic version of that pioneer drug which has been approved by the FDA is available.

C. Prescriptions for Generic Drugs

29. Generic drugs are drugs that the FDA has found to have the same active chemical composition and provide the same therapeutic effects as the pioneer, brand-name drugs. Where

a generic drug is completely equivalent to a pioneer or brand-name drug, the FDA assigns the generic drug an “AB” rating.

30. If a generic version of a brand-name drug exists and the physician has not specifically indicated on the prescription “DAW” or “dispense as written” (or similar indications, the wording of which varies slightly from state to state), then: (a) for consumers covered by most insurance plans, the pharmacist will substitute the generic drug; and (b) for consumers whose purchases are not covered by insurance plans, the pharmacist will offer the consumer the choice of purchasing the branded drug, or the AB-rated generic at a lower price.

31. Once a physician writes a prescription for a brand-name drug such as Effexor XR, that prescription defines and limits the market to the drug named or its AB-rated generic equivalent. Only drugs which carry the FDA’s AB generic rating may be substituted by a pharmacist for a physician’s prescription for a brand-name drug.

D. Abbreviated New Drug Applications For Generic Drugs

32. Congress enacted the Hatch-Waxman Act in 1984 to establish an abbreviated process to expedite and facilitate the development and approval of generic drugs. Consumers benefit from the choice and competition. To effectuate its purpose, the Hatch-Waxman Act permits a generic drug manufacturer to file an Abbreviated New Drug Application (“ANDA”), which incorporates by reference the safety and effectiveness data developed and previously submitted by the manufacturer of the original, pioneer drug. The Hatch-Waxman Act also provides an economic incentive to the first ANDA filer for a particular generic drug: a 180-day statutory period of market exclusivity, during which time the manufacturer has the right to market its drug free from competition from other generic manufacturers.

33. The ANDA must include information concerning the applicant’s position *vis-a-*

vis the patent that the pioneer drug manufacturer claims applies to the drug. Therefore, the ANDA filer must make one of four certifications:

- (a) that no patent for the pioneer drug has been filed with the FDA (a “Paragraph I Certification”);
- (b) that the patent for the pioneer drug has expired (a “Paragraph II Certification”);
- (c) that the patent for the pioneer drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a “Paragraph III Certification”); or
- (d) that the patent for the pioneer drug is invalid or will not be infringed upon by the proposed generic company’s product (a “Paragraph IV Certification”).

21 U.S.C. § 355(j)(2)(A)(vii). In the case of a patent that has not yet expired, the ANDA applicant’s only certification options are Paragraph III or IV Certifications.

34. If the ANDA contains a Paragraph IV Certification, the ANDA applicant must provide notice to the owner of each patent that is referred to in the certification, and to the holder of the approved NDA to which the ANDA refers. *See* 21 U.S.C. § 355(j)(2)(B)(I). The notice must include a detailed statement of the factual and legal basis for the ANDA applicant’s assertion that the patent is not valid or will not be infringed by the generic product. *See id.*; 21 C.F.R. § 314.95.

35. The brand-name drug patent owner, upon receiving a Paragraph IV Certification from an ANDA applicant, has 45 days to initiate a patent infringement suit against the applicant. *See* 21 U.S.C. § 355(j)(5)(iii). If no action is initiated within 45 days, the process for FDA

approval of the generic product is not delayed by patent issues. However, if a patent infringement suit is brought within the 45-day window, FDA approval of the ANDA is automatically postponed until the earliest of the expiration of the patents, the expiration of 30 months from the patent holder's receipt of notice of the Paragraph IV Certification, or a final judicial determination of non-infringement.

36. Accordingly, brand-name drug patent holders need only to file a patent infringement lawsuit within 45 days of receipt of Paragraph IV Certification in order to automatically block an ANDA applicant's generic drug from entering the market for up to 30 months.

37. An improper Orange Book listing also has additional anti-competitive effects because the first generic company to file an ANDA with a Paragraph IV Certification is, upon FDA approval, granted a 180-day period of exclusivity in relation to other generic manufacturers. 21 U.S.C. § 355(j)(5)(B)(iv). This 180-day exclusivity against other generic competitors is awarded to the first Paragraph IV filer regardless of whether or not the brand company institutes pre-approval patent infringement litigation in response to the Paragraph IV certification. Absent an improper Orange Book listing, no Paragraph IV certification would be required and, thus, no generic company would receive 180-day exclusivity.

38. Hatch-Waxman also provides brand name manufacturers with other opportunities to obtain protection from generic competition. For example, if the FDA approves an NDA involving a new chemical entity ("NCE"), the brand manufacturer filing the NDA may obtain five years of exclusivity from the date of approval of the NDA. In addition, if an NDA drug treats a rare condition, the FDA may, if appropriate, grant an additional two years of "Orphan Drug" exclusivity.

II. Facts Related to Wyeth and Effexor XR

A. Wyeth's Original Compound Patent for Effexor

39. On August 13, 1985, the (PTO) issued U.S. Patent No. 4,535,186 (the "Husbands Patent") for the compound venlafaxine hydrochloride ("venlafaxine"). The inventors, G.E. Morris Husbands, John P. Yardley, and Eric A. Muth, assigned the Husbands patent to American Home Products, now known as Wyeth.

40. Eight years later, on December 28, 1993, the FDA approved Wyeth's ANDA for Effexor, an antidepressant whose active pharmaceutical ingredient is venlafaxine. Effexor is a tablet that dissolves quickly, resulting in a rapid increase in blood plasma levels of venlafaxine shortly after administration. Compounds with such rapid dissolution profiles are referred to as "instant release" formulations. Levels of venlafaxine in the blood decrease over time, reaching subtherapeutic levels in about twelve hours. Effexor is thus usually taken twice a day.

41. The Husbands Patent protected Wyeth's venlafaxine products by preventing equivalents from entering the market until June 13, 2008 (expiration of the patent would have occurred years earlier, but Wyeth received a significant extension to reflect the NDA approval time period for Effexor, and an additional six-month extension for having conducted pediatric studies). As a result, Wyeth would have market exclusivity for both instant release and extended release venlafaxine hydrochloride for 14½ years. This lawful period of market exclusivity would enable Wyeth to market its venlafaxine products - both Effexor and Effexor XR - without generic competition, resulting in huge sales and profits to Wyeth. However, after the expiration of the patents at the end of those 14½ years, generic manufacturers of generic drugs for Effexor XR would be allowed to compete.

B. Wyeth's Plans to Extend Monopoly

42. Although the original Husbands Patent with extensions gave Wyeth 14½ years of market exclusivity for venlafaxine products, Wyeth sought to extend the period even further. Wyeth wanted patents for the routine development of extending the release of venlafaxine, although it knew these developments were in no way new inventions.

43. In the 1990's, methods for achieving sustained or extended release of the active ingredient in pharmaceuticals were well known in the industry. It was common knowledge that the rate of drug release from solid dosage forms could be extended by: (a) modifying drug dissolution through use of barrier coatings that controlled access of biologic fluids to the drug; (b) controlling drug diffusion rates from dosage forms' and (c) using chemical reactions or interactions between the drug substance or its pharmaceutical barrier and site-specific biologic fluids. Sustained or extended release dosages use methods such as coated beads, granules, and microspheres; micro-encapsulated drugs; sustained-release, extended-release, timed-release, controlled-release, or continuous-release tablets or capsules; or embedding the drugs in slowly eroding or hydrophilic matrix systems.

44. Given the industry's knowledge and prior art, Wyeth knew it would be difficult, if not impossible, to legitimately obtain a patent for extended release formulations of venlafaxine. Even if a particular formulation could be patented, the patent would prevent generic manufacturers from designing around the formulation patents and developing non-infringing formulations of extended release venlafaxine.

45. Consequently, Wyeth decided to seek "method of use" patents, and set out to patent independent claims that broadly covered methods of using extended release venlafaxine, methods that were not tied to any specific formulation. Wyeth knew that there must be something new, novel, or surprising about the methods of use in order to make its extended

release venlafaxine patentable.

46. On March 25, 1996, the Wyeth applicants filed their first application for a series of method of use patents for extended release venlafaxine. Two months later, on May 16, 1996, Wyeth sought FDA approval to sell an encapsulated extended release formulation of venlafaxine called Effexor XR. The extended release methodology for venlafaxine used for Effexor XR contained no new patentable invention in the field of pharmaceutical formulations. On October 20, 1997, the FDA approved Wyeth's NDA for Effexor XR. Effexor XR is typically taken once a day.

47. Even without patent protection beyond the original compound patent, Wyeth would still enjoy more than ten years of market exclusivity for Effexor XR. However, without another patent, Effexor XR would face generic competition by June of 2008, the expiration date of the Husbands Patent.

C. Wyeth's Three Method of Use Patents for Effexor XR

48. Wyeth submitted six sequential applications that led to three method of use define patents, the '171, '958, and '120 patents. All three patents are, and have always been, unenforceable; they only issued because Wyeth defrauded the PTO. These patents prevented generics versions of Effexor XR from coming to market in June of 2008.

1. The Application History of the '171, '958, and '120 Patents

a. The Original '006 Application

49. On March 25, 1996, the Wyeth applicants filed a provisional utility patent application, No. 60/014,006 (" '006 application") with the PTO. A utility patent application seeks to protect a new, useful, or nonobvious process or composition. Provisional patent applications require only a brief written description of the claimed subject matter. Inventors

must file a non-provisional application with formal claims within one year. Filing a provisional application essentially allows an inventor to establish a date of invention one full year before the inventor actually submits evidence of his invention's patentability.

b. The '137 Application

50. Almost exactly one year after filing the provisional application, on March 20, 1997, the Wyeth applicants filed a non-provisional application, No. 08/821,137 (" '137 application"). The '137 application claimed priority to the '006 application - meaning that the patentability of the '137 application would be evaluated as though it were filed a year earlier. The examiner required the Wyeth applicants to amend certain claims in light of prior art. On August 5, 1997, the PTO examiner issued a Notice of Allowance for the amended claims. Despite the notice of allowance, the Wyeth applicants abandoned the '137 application.

c. The '328 Application

51. On November 5, 1997, the Wyeth applicants filed a continuation-in-part application, No. 08/964,328 (" '328 application"). A continuation-in-part application repeats most of an earlier parent application but adds information that was not disclosed in the previous application. A continuation-in-part application must be filed while the earlier application is still pending.

52. The '328 application claimed priority to the '137 application and the '006 application. The examiner allowed some claims and rejected others in light of prior art. On February 16, 2000, the Wyeth applicants abandoned the '328 application - including the allowed claims.

d. The '629 Application and '171 Patent

53. On January 20, 2000 - one month before abandoning the '328 application - the

Wyeth applicants filed a continuation-in-part application, No. 09/488,629 (“ ‘629 application”) that claimed priority to the ‘328 application, the ‘137 application, and the ‘006 application. The examiner allowed some claims and rejected others. The Wyeth applicants canceled one claim, amended other claims, and added new claims. The examiner allowed the claims as amended.

54. On August 14, 2001, the ‘629 application issued as U.S. Patent No. 6,274,171 B1 (“ ‘171 Patent”). The ‘171 Patent contains 25 claims in total, including claims for (i) an extended release form of venlafaxine hydrochloride with spheroids; (ii) independent method of use claims for decreasing the incidence of nausea and vomiting; and (iii) independent method of use claims for minimizing the troughs and peaks in drug concentration in patient’s blood plasma. The ‘171 Patent expires on March 20, 2017.

e. The ‘412 Application and ‘958 Patent

55. On June 19, 2001 two months prior to the issuance of the ‘171 patent the Wyeth applicants filed a divisional application, No. 09/884,412 (“ ‘412 application”). A divisional application is an application for an independent or distinct invention disclosing and claiming only a portion of the subject matter disclosed in an earlier application. The ‘412 application claimed priority to the ‘629 application (which resulted in the ‘171 Patent), the ‘328 application, the ‘137 application, and the ‘006 application. The examiner rejected some claims and allowed others. The Wyeth applicants then canceled one claim and added new claims that were substantially similar to claims issued in the ‘171 patent.

56. On July 16, 2002, the ‘412 application issued as U.S. Patent No. 6,419,958 B2 (“‘958 Patent”). The ‘958 Patent includes claims for (i) methods of use to decrease the incidence of nausea and vomiting and (ii) methods of use for minimizing the troughs and peaks in drug concentration in patient’s blood plasma. The ‘958 Patent included a terminal disclaimer that

Wyeth did not seek an additional time period of patent protection beyond that afforded by the ‘171 Patent - that is, through March 20, 2017.

f. The ‘965 Application and ‘120 Patent

57. On September 12, 2001, Wyeth filed a continuation application, No. 09/950,965 (“ ‘965 application”) that claimed priority to ‘412 application (which resulted in the ‘958 Patent), the ‘629 application (which resulted in the ‘171 Patent), the ‘328 application, the ‘137 application, and the ‘006 application. The examiner rejected some claims and allowed others. Wyeth amended some claims to overcome the rejections. The examiner allowed the amended claims.

58. On June 11, 2002, the ‘965 application issued as U.S. Patent No. 6,403,120 B1 (“ ‘120 Patent”). The ‘120 Patent contains 14 claims, all reciting a method of use for reducing the incidence of nausea and vomiting. The ‘120 Patent also expires on March 20, 2017.

2. The Claim on Reduction in Nausea and Emesis

a. Wyeth Claimed Effexor XR Significantly Reduced the Incidence of Nausea and Emesis Associated with Effexor

59. In order to obtain a patent that protects a specific method of using a product, the applicants must have a legitimate basis for claiming that the method actually accomplishes what the applicants claim. That is, the applicants cannot just claim a method of using a pharmaceutical that reduces nausea; applicants must have a basis for claiming that the method of use reduces nausea and the method of use must actually reduce nausea.

60. In the original ‘006 provisional application, the Wyeth applicants claimed its patentable invention concerned a 24-hour extended release dosage formulation of venlafaxine that “provides a lower incidence of nausea and vomiting than the conventional tablets.”

Specifically, the Wyeth applicants told the PTO that the use of the once-a-day capsules later marketed as Effexor XR reduced “the level of nausea and incidence of emesis [that is, vomiting] that attends the administration of multiple daily dosing.”

61. In support of this statement, the Wyeth applicants claimed clinical data showed that the incidence of nausea in people taking extended release venlafaxine was significantly less than in patients taking instant release venlafaxine:

In clinical trials of venlafaxine hydrochloride ER, the probability of developing nausea in the course of the trials was greatly reduced after the first week. Venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies.

The Wyeth applicants made the same claim, repeating the exact same language, in the specifications accompanying the ‘137 application, the ‘328 application, the ‘629 application, the ‘412 application, and the ‘965 application. The exact same language appears in the ‘171 Patent, the ‘958 Patent, and the ‘120 Patent.

62. The Wyeth applicants claimed that in light of the clinical data, it was entitled to method of use patents for the reduction in the incidence of nausea and emesis:

Thus, in accordance with this use aspect of the invention there is provided a method for reducing the level of nausea and incidence of emesis attending the administration of venlafaxine hydrochloride which comprises dosing a patient in need of treatment with venlafaxine hydrochloride with an extended release formulation of venlafaxine hydrochloride once a day in a therapeutically effective amount.

The Wyeth applicants made the same claim, repeating the exact same language, in the specifications accompanying the ‘137 application, the ‘328 application, the ‘629 application, the ‘412 application, and the ‘965 application. The exact same language appears in the ‘171 Patent, “958 Patent, and ‘120 Patent specifications.

63. The Wyeth applicants did not provide the PTO with any other evidence of Effexor XR's ability to reduce the incidence of nausea or vomiting. Wyeth did not disclose to the PTO which studies showed the reported reductions; nor did Wyeth disclose to the PTO the raw data collected in these studies. Wyeth's sole support for its method of use claim for the reduction of vomiting and emesis was the express representation that two eight-week and one twelve week clinical studies demonstrated that Effexor XR "showed a statistically significant improvement" in the incidence of nausea and emesis over conventional Effexor.

b. The Clinical Data Did Not Show That Effexor XR Significantly Reduced the Incidence of Nausea and Emesis

(1) None of the Three Studies Showed a Reduction in Nausea or Emesis

64. Only years later during patent infringement litigation with potential competitors did Wyeth identify the two eight-week and one 12-week studies, designated as 600B-208-US ("study 208"), 600B-209-US ("study 209"), and "600B-367-EU ("study 367"). Wyeth relied on these studies in seeking FDA approval of Effexor XR, but never identified them to the PTO.

65. Study 208 was a double-blind, flexible dose, twelve-week efficacy study of Effexor XR, Effexor, and placebo in outpatients with major depression.

66. Study 209 was a double-blind, flexible dose, eight-week study of Effexor XR and placebo in outpatients with major depression. Study 209 did not use instant release Effexor as a comparator.

67. Study 367 was a double-blind, flexible dose, eight-week efficacy study of Effexor XR, the competing antidepressant Paxil, and placebo in outpatients with major depression. Study 367 did not use instant release Effexor as a comparator.

68. None of these three clinical studies showed that Effexor XR had a statistically

significant improvement in the incidence of nausea over Effexor.

69. Studies 209 and 367 could not possibly have shown a reduction in nausea and emesis over conventional Effexor because they did not include a group of patients taking instant release Effexor. Only Study 208 included both patients receiving Effexor XR and patients receiving Effexor, and therefore could have allowed Wyeth to compare the incidence of nausea between the Effexor and Effexor XR groups.

70. Moreover, Study 208 did not show a “statistically significant improvement” over Effexor. In fact, according to a published article describing the study, the incidence of nausea was exactly the same in the Effexor XR and the Effexor groups, 45%. *See* Lynn M. Cunningham et al., Once-Daily Venlafaxine Extended Release (XR) and Venlafaxine Immediate Release (IR) in Outpatients with Major Depression, 9(3) ANNALS OF CLINICAL PSYCHIATRY 157 (1997). Wyeth never disclosed this article, published years before the method of use patents issued or its conclusions about rates of nausea to the PTO in any of its patent applications.

71. Study 208 also suffered from serious data corruption. The principal investigator of one of the study sites, Bruce Diamond, Ph.D., and one of his subinvestigators, Richard Borison, M.D., Ph.D., were indicted for diversion of research funds on February 19, 1997, almost a full year after Wyeth claimed clinical data showed a significant reduction in the incidence of nausea with Effexor XR based in part of the results of Study 208. Upon learning of these indictments, the FDA noted that the data from Study 208 was “of uncertain reliability” and asked Wyeth to reanalyze the data from Study 208, excluding the data from the corrupted site. Wyeth provided a reanalyzed data to the FDA. Wyeth never informed the PTO about the corrupted data, and never provided reanalyzed data - or any data from Study 208 - to the PTO.

72. In September 2004, Wyeth submitted a further revised version of the final clinical report for Study 208. Although characterized as “minor corrections,” the revisions included two revised analyses of the data on nausea. These revised analyses were never submitted to the PTO.

**(2) Pooled Study Data Did Not Show a
Reduction in Nausea or Emesis**

73. The Wyeth applicants told the PTO that each of the three studies independently showed a statistically significant improvement in the incidence of nausea and emesis. Wyeth later claimed, in litigation with the generics, that it had not intended to claim the studies independently showed these results, but that “pooled” data showed the professed reduction in nausea and emesis. However, even if the data from all three studies were combined, or “pooled,” it does not show a statistically significant reduction in the incidence of nausea or emesis.

74. First, because two of the studies did not include an Effexor treatment group, at best the data from the Effexor XR treatment groups in Studies 208, 209, and 367 could be pooled and compared only to the conventional Effexor treatment group in Study 208. This type of comparison is scientifically inappropriate, and cannot support a claim that one drug has fewer instances of side effects than another drug (particularly in light of the problems with the data from Study 367, discussed below). The combination or “pooling” of patient data from Studies 208, 209, and 367 would be statistically biased, and thus an improper basis for reaching a conclusion that there is a statistically significant improvement in nausea by patients taking Effexor XR as compared to patients taking instant release Effexor

75. Second, even if this inappropriate pooling is done, it does not show a statistically significant difference in nausea and emesis.

76. At the time in 1996, when the Wyeth applicants submitted the original ‘006

application, Wyeth had not “pooled” the data from Studies 208, 209, and 367. A decade later, during patent infringement litigation with the generics, Wyeth had its Rule 30(b)(6) deposition witnesses (Dr. Mangano and Dr. Alaburda) present new, never-before seen, calculations allegedly based on the original clinical study data that purportedly showed a diminished incidence of nausea and emesis. These calculations were done ten years after the clinical studies were completed and nine years after the Wyeth applicants told the PTO that extended release venlafaxine reduced the incidence of nausea.

77. Drs. Mangano and Alaburda testified that, according to yet another Wyeth employee Wilfredo Ortega-Leone, the Wyeth applicants’ claim that Effexor XR reduced the incidence of nausea was based on pooling the nausea data for the Effexor XR treatment groups in Studies 208, 209, and 267 and comparing that data to nausea data for conventional Effexor treatment groups in entirely different (undisclosed) studies. Comparing different treatment groups from entirely different studies is wholly inappropriate, statistically biased, and is not a legitimate basis for claiming that one drug has fewer side effects than another drug. Moreover, Wyeth never disclosed its statistical analysis and underlying assumptions.

78. In fact, the only reason that pooled Effexor XR data might possibly have shown a reduction in nausea (as compared to unrelated study data for conventional Effexor) is because it included the results of Study 367. Study 367 reported markedly fewer instances of nausea in the Effexor XR treatment group than were reported by the Effexor XR treatment groups in Studies 208 and 209. Study 367 was conducted in Europe. Studies 208 and 209 were conducted in the United States. Using the same extended release formulation, the European population in Study 367 reported a 17% incidence of nausea, while the U.S. population in Study 209 reported a 36% incidence of nausea.

79. The Wyeth applicants knew, and it was well known at the time, that the European population has a significantly greater tolerance for, and/or underreports, side effects such as nausea and vomiting than the U.S. population. By including the European XR data, it would look like Effexor XR reduced the incidence of nausea, when the real cause of the ostensible reduction in nausea was a known population difference. The Wyeth applicants did not disclose to the PTO that the claimed reduction in nausea and emesis was a result of studying a population less likely to experience and/or report side effects.

80. Further, as the FDA confirmed when analyzing Effexor XR's efficacy, Study 367 was a complete and utter failure: "study 367 provided no persuasive evidence of antidepressant efficacy for venlafaxine ER." The Wyeth applicants never disclosed to the PTO that Study 367 failed to show that Effexor XR was effective.

(3) The FDA Refused to Pool Side Effect Data From the 208, 209, and 367 Studies

81. In applying for FDA approval of Effexor XR, Wyeth argued that the FDA should evaluate the incidence of adverse events, including nausea, by pooling the data from studies 208, 209, and 367.

82. The FDA disagreed. On August 13, 1997, the FDA noted that "the incidence of many adverse events in the European study seemed to be substantially lower than in the two domestic studies" and determined that Study 367 could not be included in the pooled data used to assess the adverse events associated with Effexor XR:

The incidence of many important adverse events appeared to be lower in the European study (367) compared to both U.S. studies (208 and 209). Primarily for this reason, study 367 was not considered poolable with studies 208 and 209 for purposes of delineating the common adverse event profile of Effexor XR.

83. The FDA noted that including Study 367's data in the pooled adverse event data

would result in a marked reduction in the number of adverse events described on the drug's label. If data from Studies 208, 209, and 367 were pooled, the Effexor XR label would have listed only eight common drug-related adverse events. In contrast, when only the data from Studies 208 and 209 were pooled, the Effexor XR label would have listed an additional four common drug-related adverse events. The FDA noted that "Effexor XR is placed in a more favorable light if [Wyeth's proposed] pool is used."

84. Further, the FDA ultimately permitted Wyeth to pool data from Studies 208 and 209, but not for the purpose of comparing the incidence of side effects between extended release venlafaxine and instant release venlafaxine. The FDA noted that "the pool of the two domestic studies [Studies 208 and 209] allows for a more conservative presentation of adverse event data in labeling and since Effexor XR will be marketing in the U.S., the pool of the two U.S. studies may be more relevant." The FDA's refusal to pool data from all three studies occurred only a year after Wyeth filed the original '006 application, well before Wyeth filed its subsequent patent applications, and almost 4 years before the first method of use patent issued.

85. Wyeth knew that including the results of European Study 367 skewed the incidence of adverse events (including nausea) because the FDA told them so at least four years before the '171 Patent issued, a patent whose claims were premised on Effexor XR's reported ability to reduce the incidence of nausea experienced by patients taking instant release Effexor. However, the Wyeth applicants never informed the PTO that the FDA refused to include the data from study 367 when analyzing the incidence of adverse events associated with Effexor XR - that is, that the FDA refused to assess the incidence of side effects by pooling the data from Studies 208, 209, and 367.

86. The FDA-approved package insert for Effexor XR does not contain any

representation that Effexor XR showed a statistically significant improvement in nausea over Effexor, even though the package insert compares Effexor XR and Effexor as to the potential for other adverse reactions in the course of their administration.

c. Wyeth Intended for the PTO to Rely on Its Material Misrepresentations

87. The Wyeth applicants intended to deceive the PTO with their misrepresentations about nausea.

88. The Wyeth applicants repeatedly made misrepresentations about the incidence of nausea associated with Effexor XR during the prosecution of the '137 Application, the '328 Application, and each of the method of use patents. The Wyeth applicants affirmatively and repeatedly misrepresented that they possessed three clinical studies that showed Effexor XR significantly reduced the incidence of nausea and emesis associated with Effexor. The Wyeth applicants further affirmatively misrepresented that venlafaxine ER greatly reduced the probability of developing nausea. Specifically, the Wyeth applicants knowingly included the following sentences in the patent specifications submitted to the PTO:

In clinical trials of venlafaxine hydrochloride ER, the probability of developing nausea in the course of the trials was greatly reduced after the first week. Venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies.

89. The Wyeth applicants knew these misrepresentations were false.

(a) they knew the only study directly comparing Effexor XR and Effexor (Study 208) did not show the claimed statistically significant improvement.

(b) they knew Wyeth was not in possession of three clinical studies that showed the claimed statistically significant improvement in nausea.

(c) they knew that two out of the three referenced studies did not even compare Effexor XR to Effexor.

(d) they knew that any claimed reduction in nausea and emesis was a result of conducting Study 367 among a population that notoriously reports fewer side effects, such as nausea and emesis.

(e) they knew that the claimed reduction in nausea and emesis could only be supported, if at all, by inappropriately comparing different treatment groups across different studies.

(f) they knew the FDA had refused to pool the data from Studies 208, 209, and 367 when analyzing the incidences of side effects associated with extended release venlafaxine.

90. The Wyeth applicants knew the PTO would read the patent specifications submitted with their various patent applications and thus receive their misrepresentations about Effexor XR's effectiveness in treating nausea and about the results of the three references clinical studies.

91. Each individual associated with the filing and prosecution of a patent application has a duty to disclose all information known to that individual to be material to patentability. 37 C.F.R. §1.56. Information is material if it establishes unpatentability, whether by itself or in combination with other information, or if it refutes or is inconsistent with a position taken by an applicant in arguing for patentability. The Wyeth applicants were aware of their individual obligations to disclose material information, and signed certifications acknowledging this duty.

92. The Wyeth applicants knew that their misrepresentations about nausea were material. No nausea method of use claims could have been patented in light of the truth:

extended release venlafaxine did not meaningfully reduce the incidence of nausea; Wyeth did not have clinical data from three studies that showed a reduction in nausea; and pooled data from three studies did not show a reduction in nausea.

93. The Wyeth applicants also failed to inform the examiner about the Cunningham article (reporting results from Study 208) and the FDA's refusal to pool the data. Both were material: a reasonable Patent examiner would want to know about contradicting published materials and another agency's determination about pooling.

94. The Wyeth applicants knew there was a substantial likelihood the PTO would rely on their misrepresentations about nausea in evaluating their numerous nausea method of use claims because the Wyeth applicants did not provide any other evidence that extended release venlafaxine reduced nausea.

95. The PTO did, in fact, rely on the Wyeth applicants' misrepresentations. In the absence of any other basis for substantiating Wyeth's nausea claim, the PTO relied on the singular, but oft-repeated, statement that clinical studies showed Effexor XR reduced the incidence of nausea and emesis as compared to Effexor in approving twenty claims that began by reciting a method of use that reduces nausea and emesis:

A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof

96. The misrepresentation of the highly material information with a high level of intent to deceive the PTO, coupled with a lack of good faith on the part of the inventors or their attorneys, renders the method of use claims for reducing nausea invalid and/or unenforceable. Specifically, the nausea fraud directly affects claims 20, 22, and 23 of the '171 Patent; claims 1, 3, and 4 of the '958 Patent; and all of the claims of the '120 Patent. Moreover, all three patents

are rendered entirely invalid and unenforceable as a result of the fraud related to the claims about nausea.

3. The Claim That Wyeth was the First to “Unexpectedly” Discover Extended Release Venlafaxine

97. An applicant can obtain a patent only if he is the first to invent the subject matter described in the patent application. If earlier publications or patents disclose the invention, or it can be established that someone else invented the subject matter, the invention is not patentable.

35 U.S.C. § 102. Prior invention of the subject matter by someone else may be demonstrated by:

- Printed publications that describe the invention, either in the U.S. or internationally, before the patent applicant invented the invention (35 U.S.C. 102 § (a));
- A printed publication that describes the invention, published more than one year before the patent applicant filed a patent application for it (35 U.S.C. 102 § (b));
- A U.S. patent application filed by another inventor describing the invention before the patent applicant invented the invention (35 U.S.C. §102(e)); and/or
- Evidence of earlier invention by another, including non-public disclosures (35 U.S.C. § 102 (f); *OddzOn Products, Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1403 (Fed. Cir. 1997)).

98. Throughout the prosecution of the method of use patents, the Wyeth applicants fraudulently misrepresented Wyeth’s “unexpected” discovery of extended release venlafaxine to the PTO. Wyeth represented in all of its applications for the method of use patents that it was “completely unexpected that an extended release formulation containing venlafaxine could be obtained.” The Wyeth applicants first made this representation in the provisional ‘006 application, filed on March 25, 1996. All of the method of use patents include this language, the last of which issued on July 16, 2002 (the ‘958 Patent).

99. However, an extended release version of venlafaxine was not at all unexpected to

Wyeth. The Wyeth applicants were aware of extended release versions of venlafaxine before filing the '006 application. Wyeth's own Upton patent disclosed extended release venlafaxine. Wyeth also knew that its collaborator Alza Corporation ("Alza") had filed an application to patent a version of extended release venlafaxine before Wyeth filed the '006 application.

100. The Wyeth applicants had multiple opportunities to amend the specifications in its various applications to no longer assert that extended release venlafaxine was surprising or unexpected and failed to do so. Wyeth knew that by making such an amendment, it would no longer be able to claim priority back to the date of the '006 application. Without the '006 application's priority date, Wyeth would not have been able to patent any version of Effexor XR.

a. Wyeth's Upton Patent Disclosed Extended Release Venlafaxine

101. Wyeth's own Upton Patent disclosed extended release venlafaxine. Wyeth applied for the Upton Patent on January 30, 1995, more than a year before Wyeth claimed that extended release venlafaxine was surprising in the '006 application. The Upton Patent issued to Wyeth on April 9, 1996, one month after Wyeth filed the '006 provisional application and years before the method of use patents issued during the period August 2001 - July 2002. This disclosure makes an extended release formulation of venlafaxine not at all surprising, especially not to Wyeth.

102. The Upton Patent qualifies as prior art under 35 U.S.C. §102(e) and 35 U.S.C. §102(f).

b. Alza's '589 PCT Application Disclosed Extended Release Venlafaxine

103. In 1992, Wyeth entered into an agreement with Alza to develop an extended release formulation of venlafaxine using Alza's proprietary drug delivery systems. Alza knew

Wyeth was simultaneously developing an extended release version of venlafaxine in house.

104. The agreement granted Alza ownership rights in any information generated or acquired during the collaboration and the patents result from the collaboration. Alza also retained the right to use, disclose, and license information from the collaboration to third parties.

105. The collaboration agreement required Alza and Wyeth to exchange information about their respective efforts to develop extended release venlafaxine. The parties' Scientific Steering Committee, comprised of Alza and Wyeth employees, held one or more meetings that discussed the progress of the collaboration and other confidential information about the project, including the status of patent application filings and patent prosecution.

106. On May 27, 1993, Alza filed patent application U.S. Serial No. 08/068,480, listing inventors Edgren, *et. al* (the "Edgren application"). The Edgren application disclosed venlafaxine. The status of the prosecution of the Edgren application was discussed at multiple Scientific Steering Committee meetings between Wyeth and Alza pursuant to the collaboration agreement. The Edgren application eventually matured into U.S. Patent 6,440,457 on August 27, 2002 (the "Edgren Patent").

107. On December 8, 1994, the World Intellectual Property Organization in Geneva, Switzerland published WO 94/27589, assigned to Alza (the "'589 PCT application"). The '589 PCT application claims priority to the Edgren application. The '589 PCT application discloses once-a-day venlafaxine extended release formulations, methods for the administration of venlafaxine extended release formulations, and the hours required for *in vitro* dissolution.

108. Alza wanted to develop formulations that provided for a controlled rate of drug release over an extended period of time. As Alza explained in the '589 PCT application, conventional instant release formulations result in "large peaks and valleys ... in the drug blood

levels.” The applicants stated that there was a “need for a controlled-release dosage form that can administer the drug at a controlled rate over an extended time to provide constant therapy and thereby eliminate the need for multiple dosing.” The Alza formulations were designed to “provide a drug delivery controlled release system that can deliver a drug for maintaining constant drug levels in the blood, thereby functioning as a controlled release system.” Alza further sought “to provide a once a day controlled release dosage form to deliver [venlafaxine hydrochloride] orally to a patient in need of therapy[.]” and “to provide a method for administering [venlafaxine hydrochloride] in a therapeutic range while simultaneously avoiding a toxic range[.]”

109. The ‘589 PCT application disclosed venlafaxine specifically as the antidepressant pharmaceutical ingredient. The formulations were to be administered in a single dose over a twenty-four hour period. The ‘589 PCT application indicated that the dosage form successfully maintained constant drug levels in the blood by virtue of its extended release properties.

110. While the ‘589 PCT application and Edgren Patent do not report peak blood plasma levels, minimization of the troughs and peaks of blood plasma level are inherent in the extended release formulations disclosed in the ‘589 PCT application and the Edgren Patent. Any skilled practitioner of the art can see that the Alza formulation for controlled release venlafaxine formulations eliminated peaks and troughs of drug concentration in a patient’s blood plasma that occurred in the therapeutic metabolism of multiple daily doses of venlafaxine.

111. Both the Edgren Patent and the ‘589 PCT application qualify as prior art to the method of use patents. The earliest date of invention for Wyeth’s extended release formulations is March 25, 1996, the filing date of the ‘006 provisional application.

112. The ‘589 PCT application was published on December 8, 1994, over a year before

Wyeth filed the '006 application. The '589 PCT application qualifies as prior art against the method of use patents as a printed publication published in a foreign country before Wyeth invented venlafaxine extended release. 35 U.S.C. §102(a). The '589 PCT application further qualifies as prior art against the method of use patents as printed publications published more than one year before Wyeth filed the '006 provisional application. 35 U.S.C. §102(b).

113. The Edgren application was filed with the PTO on May 27, 1993, roughly three years before Weyth invented extended release venlafaxine (as claimed in the '006 provisional application). The Edgren inventors disclosed an extended release venlafaxine formulation that maintained a constant level of venlafaxine in a patient's plasma over a twenty-four period, which can reduce toxic effects. Thus, the Wyeth inventors are not the first to invent the broadly recited method of reducing toxic effects (such as nausea and emesis) or methods of eliminating the peaks and troughs (i.e., maintaining a constant level) of drug in a patient's plasma over a twenty-four period. 35 U.S.C. § 102(t).

114. The Edgren patent qualifies as a patent defeating prior art against the method of use patents, since the application was filed in the U.S. before Wyeth invented its controlled release formulation of venlafaxine. 35 U.S.C. 102(e).

**c. Wyeth Intentionally Deceived the PTO by
Falsely Claiming it Was the First to Discover,
“Unexpectedly,” Extended Release Venlafaxine**

115. The Wyeth applicants knowingly withheld highly material information from the PTO with the intent to deceive the PTO. The Wyeth applicants had a duty to present all information that was known to be material to the patentability of the claims to the examiner. Information that is non-public, but known to the applicant, can be material to patentability. The Wyeth applicants breached their duty of candor to the PTO by failing to properly disclose

Wyeth's collaboration agreement with Alza, the '589 PCT application, and the Edgren application.

116. Prior to applying for and prosecuting the method of use patents, Wyeth knew about the Edgren application and the '589 PCT application -- from its participation in the Scientific Steering Committee with Alza under the terms of their collaboration agreement.

117. The Wyeth applicants were aware that the '589 PCT application discloses "controlled release dosage forms" of venlafaxine. The Wyeth applicants were similarly aware the PCT application claimed priority back to May 27, 1993, well before Wyeth claimed to have invented its extended release venlafaxine. Wyeth and Wyeth Attorney Arthur G. Seifert disclosed the existence of the '589 PCT application to the PTO on an IDS sent to the PTO on August 13, 1998, during the prosecution of the '328 application. Wyeth also did not disclose the '589 PCT Application during the prosecution of the earlier '137 application.

118. Despite their knowledge of the disclosures in the '589 PCT application, the Wyeth applicants each nonetheless continued to misrepresent to the PTO that "[i]t was completely unexpected that an extended release formulation containing venlafaxine hydrochloride could be obtained."

119. The collaboration agreement and the resulting '589 PCT application were material to patentability because they presented a *prima facie* case of invalidity as a prior invention of another. Wyeth inventors Sherman, Clark, Lamar and White were not the first to invent methods of (i) eliminating peaks and troughs of venlafaxine in a patient's blood plasma and (ii) reducing nausea and emesis, via once daily dosing of venlafaxine, Alza and its scientists, with the knowledge and collaboration of Wyeth, had developed technology and filed and prosecuted a patent application directed to those methods at least three years before Wyeth made

its “unexpected” discovery. The Wyeth inventors derived at least part of their invention from the collaboration with Alza.

120. The ‘589 PCT application is separately material because, contrary to Wyeth’s claims to discovery, it was not unexpected that one could make a controlled release venlafaxine product that eliminated the peaks and troughs of the drug in blood plasma or reduce the incidence of nausea.

121. It is also clear that Wyeth applicants intended to deceive the PTO, since they knew that (1) Alza was developing an extended release version of venlafaxine; (2) Alza disclosed to Wyeth that it had filed the Edgren application and reported to Wyeth on the status of the Edgren application; (3) Wyeth was aware of the ‘589 PCT application (as evidenced by its late submission of the ‘589 PCT application to the PTO); and (4) Wyeth knew the ‘589 PCT application disclosed formulations of extended release venlafaxine that minimized the troughs and peaks of the amount of venlafaxine in patients’ blood serum levels.

122. The Wyeth applicants’ intent to deceive may also be inferred from Wyeth’s financial motivation. Wyeth was aware of the impact that an Alza patent would have on Wyeth’s exclusive right to sell Effexor XR. Wyeth knew that the collaboration agreement provided that Alza would own the rights to any patent that resulted from their collaboration. Alza was free to sell, use, or license the rights to the technology to a third party. Even a patent that named both Wyeth and Alza inventors would be at least co-owned, if not completely owned, by Alza. Wyeth would no longer have a monopoly over extended release venlafaxine.

123. By withholding information about the full scope of the Alza formulations while repeatedly arguing through six patent applications that the Wyeth discovery was unexpected demonstrates that Wyeth intended to deceive the PTO.

124. The high level of materiality of the Alza formulation references as patent defeating references coupled with Wyeth's repeated intent to deceive the patent examiners as to the teachings of the references, renders the nausea and "troughs and peaks" method of use claims invalid and/or unenforceable. Specifically, Wyeth's fraud infects and renders invalid and/or unenforceable claims 20-25 of the '171 Patent and all of the claims of the '958 and '120 Patents.

4. Wyeth Failed to Disclose a Previous Examiner's Rejection of all Method of Use Claims in Light of Wyeth's Own Upton Patent.

a. Wyeth Failed to Disclose its Own Upton Patent to the Original Patent Examiner

125. On January 30, 1995, more than a year before the Wyeth applicants filed the '006 application, the Wyeth applicants filed patent application No. 08/380,093, by Upton *et al.* (the Upton application). The Upton application sought a patent for a method of using venlafaxine to treat hypothalamic amenorrhea (menopause) in non-depressed women. It did not seek approval of any formulation of venlafaxine, and it is not apparent from the face of the specification itself that it would reference any particular formulation of venlafaxine. However, included in the proposed patent specification was a single reference to a "sustained oral administration form or time-release form [of venlafaxine], which may be used to spread the dosage over time, such as for once-a-day applications."

126. On March 4, 1996, the PTO mailed Wyeth a Notice of Issue, informing Wyeth that the Upton application would issue as a patent ("Upton Patent"). Wyeth had drafted the Upton application, and the Wyeth applicants were fully aware that the Upton Patent disclosed once a day venlafaxine formulations that "spread the dosage over time." Wyeth rushed to file a provisional application that covered nausea and "troughs and peaks" claims (discussed below) to avoid the Upton Patent standing as prior art to future extended release venlafaxine claims. On

March 26, 1996, a mere 22 days after getting notice that the Upton Patent would issue, the Wyeth applicants filed the '006 application.

127. On April 9, 1996, one month after the '006 provisional application was filed, the Upton Patent issued as US. Patent No. 5,506,270. The Upton Patent was assigned to Wyeth. The Upton Patent contained the same reference to sustained and time release forms of venlafaxine as the proposed specification at column 5, lines 23-27:

It is understood that ... this invention is intended to cover any means of administration to a patient of an active amount of the compounds listed above in the treatment of hypothalamic amenorrhea. Such administrations may also be provided in a bolus form, intermittent-release form, sustained oral administration form or time-release form, which may be used to spread the dosage over time, such as for once-a-day applications.

128. This disclosure of extended release venlafaxine formulations is prior art relevant to claims made in the applications for the method of use patents. This prior art renders unpatentable other method of use claims related to spreading the dose over time (such as once-a-day dosing) and obvious consequences of spreading the dose over time (such as minimizing the "troughs and peaks" of venlafaxine in the blood and reducing nausea thought to be associated with increased levels of venlafaxine in the blood).

129. The Wyeth applicants knew the Upton Patent disclosed extended release venlafaxine. The Wyeth applicants knew this information was material. The Wyeth applicants also knew that a reasonable PTO examiner would want to know (i) that Wyeth had been prosecuting (for over a year) a patent application for a method of use for venlafaxine whose specification disclosed extended release venlafaxine; (ii) that a prior examiner had rejected the claims; and (iii) that Wyeth had agreed with that objection.

b. Examiner Hulina Rejected Wyeth's Independent Method of Use Claims for an Extended Release Venlafaxine in Light of the Upton Patent

130. On March 20, 1997, almost a year after Wyeth's Upton Patent issued, the Wyeth applicants filed the '137 application, claiming priority to the '006 application. The '137 application was assigned by the PTO to Examiner Amy Hulina.

131. Claim 1 recited an extended release formulation of venlafaxine hydrochloride with spheroids:

1. An encapsulated, extended release formulation of venlafaxine hydrochloride comprising a hard gelatin capsule containing a therapeutically effective amount of spheroids comprised of venlafaxine hydrochloride, microcrystalline cellulose and hydroxypropylmethylcellulose coated with ethyl cellulose and hydroxypropylmethylcellulose.

132. Claim 9 recited a method of use for reducing incidences of nausea and vomiting associated with venlafaxine:

9. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

133. Claim 10 recited a method of use for reducing the disparities in concentration of venlafaxine in a patient's blood serum:

10. A method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing

venlafaxine hydrochloride as the active ingredient.

134. On July 10, 1997, the Wyeth applicants submitted an Information Disclosure Statement (“IDS”) listing five U.S. Patents, no foreign patents, and no other publications. Wyeth did not list the original compound patent (the Husbands Patent) on the IDS, but referenced it in the specification. Examiner Hulina considered all 5 references reported by Wyeth. The Wyeth applicants did not list or otherwise disclose the Upton Patent. Examiner Hulina discovered Wyeth’s Upton patent in her prior art search.

135. During a telephone interview on July 30, 1997, Examiner Hulina informed Wyeth applicants Attorney Robert Boswell that independent claims 9 and 10, the nausea and “troughs and peaks” method of use claims, were not patentable as independent claims in light of the disclosure of extended release formulations of venlafaxine in the Upton Patent. She further informed Attorney Bowell that the method of use claims would only be patentable if Wyeth amended them to depend on the particular formulation of extended release venlafaxine described in claim 1.

136. The Wyeth applicants had hoped to patent independent method of use claims, claims unassociated with a particular formulation of extended release venlafaxine, in order to maximize a market exclusivity for extended release venlafaxine capsules. Independent method of use claims could be asserted against any generic manufacturer that attempted to market any formulation of extended release venlafaxine. However, dependent method of use claims could only be asserted against a generic manufacturer that happened to be using the exact same formulation of extended release venlafaxine that the method of use claims depended on. Independent method of use claims would provide further impediments to generic manufacturers, to Wyeth’s economic benefit.

137. The Wyeth applicants did not challenge Examiner Hulina's conclusion that claims 9 and 10 were unpatentable as independent claims. Rather, Wyeth applicant Attorney Boswell, agreed with the Examiner's conclusion by authorizing the examiner to amend the method of use claims in order to avoid rejection. An examiner's amendment changed Claims 9 and 10 from independent claims to dependent claims, thereby limiting the method of use claims to the specific extended release formulation of venlafaxine recited in claim 1.

138. On August 5, 1997, Examiner Hulina issued a notice of allowance for the amended, now dependent, method of use claims and the independent formulation claim, noting that "[t]he prior art does not teach or suggest the specific extended release claim formulation according to claim 1." Despite the notice of allowance, the Wyeth applicants decided to abandon the '137 application - presumably in the hopes that a new application might draw a different examiner that would be unfamiliar with the Upton Patent's disclosure of extended release venlafaxine and would, therefore, allow independent nausea and "troughs and peaks" method of use claims.

c. Wyeth Never Disclosed that the PTO Rejected its Method of Use Claims in Light of the Upton Patent

(1) Wyeth Did Not Disclose the Previous Examiner's Rejection in the '328 Application

139. On November 5, 1997, the Wyeth applicants filed the '328 continuation-in-part application. Fortunately for Wyeth, the '328 application was assigned to a different PTO examiner in a different art unit, James M. Spear in Art Unit 1615.

140. Claim 1 recited a formulation claim similar to claim 1 in the '137 application, an extended release form of venlafaxine hydrochloride with spheroids. Independent method of use

claims 13 and 14 were identical to proposed method of use claims 9 and 10 of the abandoned '137 application - claims explicitly rejected by Examiner in light of the Upton Patent's reference to an extended release form of venlafaxine, that "spread the dosage over time," claims the Wyeth applicants had agreed to amend, and claims that Examiner Hulina had allowed once amended. The '328 application did not contain any other independent method of use claims.

141. On February 9, 1998, the Wyeth applicants submitted an IDS identifying the same five U.S. Patents identified in the IDS for the '137 application as well as the Upton and Husbands Patents. No foreign patent documents or other publications were listed. Examiner Spear considered all of the references on the IDS. On August 13, 1998, the Wyeth applicants submitted a Supplemental IDS, listing three foreign patent documents (discussed infra at ¶¶ ____). Examiner Spear also considered the new submissions.

142. On October 14, 1998, Examiner Spear allowed the method of use claims (claims 13 and 14) to issue as independent claims - the very claims that Examiner Hulina had previously required Wyeth to amend to be dependent on a particular formulation. The Wyeth applicants never informed Examiner Spear of critical facts: (a) that the Upton Patent identified the existence of an extended release formulation of venlafaxine hydrochloride that rendered their method of use claims unpatentable; (b) that they had previously agreed to amend the very same claims to be dependent claims; (c) that a previous Examiner had found the exact same claims to be unpatentable.

143. That the Upton patent references a sustained release, once-a-day formulation of venlafaxine is not evident from the title of the patent: "Venlafaxine in the Treatment of Hypothalamic Amenorrhea in Non-Depressed Women." Similarly, the reference to a sustained release formulation is contained in a single sentence in the middle of a three-page single-spaced

specification; an examiner would have to review the Upton Patent very closely to find the reference that the Wyeth applicants were all too well aware of.

144. Also on October 14, 1998, Examiner Spear rejected claim 1, for a formulation with spheroids, as unpatentable in light of prior art (other than the Upton Patent). The Wyeth applicants responded to the Examiner's rejections by canceling, amending and adding new claims. On July 21, 1999, Examiner Spear rejected the new claims, stating that the Applicants' arguments to overcome the prior art were not persuasive. The Wyeth applicants responded by filing a petition for an extension of time, but never ultimately responded. On February 16, 2000, the Wyeth applicants abandoned the '328 application - including its allowed independent method of use claims.

**(2) Wyeth Did Not Disclose the Previous
Examiner's Rejection in the '629
Application**

145. On January 20, 2000, a month before abandoning the '328 application, the Wyeth applicants filed the '629 continuation-in-part application. Wyeth's latest application was again assigned to Examiner Spear.

146. The '629 application contained a nearly identical specification to the '328 application. Claim 1, again, recited an extended release version of venlafaxine hydrochloride in spheroids that was substantially similar to the claim rejected by Examiner Spear during the prosecution of the '328 application in light of the prior art. Claims 21 and 22, again, recited the same independent method of use claims originally presented in (rejected) claims 9 and 10 of the '137 application and (allowed but abandoned) claims 13 and 14 in the '328 application:

21. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis which comprises administering orally to a patient in need thereof,

an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

22. A method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

The Wyeth applicants, again, never informed Examiner Spear that the Upton Patent identified the existence of an extended release formulation of venlafaxine that rendered their method of use claims unpatentable. The Wyeth applicants never disclosed that they had agreed to amend these claims to be dependent claims in order to avoid a rejection over the prior art disclosed by Wyeth's own Upton Patent. The Wyeth applicants never disclosed to Examiner Spear that a previous Examiner determined these claims were unpatentable. On January 4, 2001, Examiner Spear allowed claims 21 and 22.

147. The Wyeth applicants then added additional method of use claims 23-26. Claims 23 and 24 recite methods of use "with diminished incidence of nausea." Claims 25 and 26 recite methods of use for "eliminating the troughs and peaks of drug concentration in a patient's blood plasma." All are substantially similar to the method of use claims rejected by Examiner Hulina. Nonetheless, in the absence of Wyeth's disclosure of her rejection and failing to directing Examiner Spear to the Upton Patent's fleeting reference to extended release venlafaxine, Examiner Spear allowed these independent method of use claims.

148. On August 14, 2001, the '629 application issued as the '171 Patent. The '171 Patent contains six independent method of use claims: claims 20 through 25. All recite either

diminished incidences of nausea or eliminating the troughs and peaks in a patient's blood plasma. (Due to renumbering, proposed claims 21 and 22 issued as claims 20 and 21. Proposed claims 23 through 26 issued as claims 22 through 25).

**(3) Wyeth Did Not Disclose the Previous
Examiner's Rejection in the '412
Application**

149. On June 19, 2001, two months before the '171 Patent issued, the Wyeth applicants filed divisional '412 application to pursue rejected claim 1 of the '629 application. The 412 application was again assigned to Examiner Spear.

150. The specification and claims of the '412 application were identical to the '629 application. The Wyeth applicants then canceled claims 2-22 and added new, independent method of use claims 23 and 24:

- 23. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis which comprises administering orally to a patient in need thereof, an extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.
- 24. A method for eliminating the troughs and peaks of drug concentration in a patients blood plasma attending the therapeutic metabolism of plural daily doses of which comprises administering orally to a patient in need thereof, an extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

151. Claims 23 and 24 are substantially the same the method of use claims originally presented in the rejected claims 9 and 10 of the '137 application, and the allowed claims 20 and 21 of the '171 Patent, differing only by no longer including the word "encapsulated." Once

again, the Wyeth applicants, (a) never informed Examiner Spear that the Upton Patent identified the existence of an extended release formulation of venlafaxine that rendered their method of use claims unpatentable; (b) never disclosed to Examiner Spear that a previous examiner determined that method of use claims substantially similar to claims 23 and 24 were unpatentable; (c) never disclosed that Wyeth had agreed to amend substantially similar claims in order to avoid a rejection over the prior art disclosed by Wyeth's own Upton Patent.

152. On January 13, 2002, Examiner Spear rejected claims 23 and 24 as being unpatentable over claims 20 and 21 of the '171 Patent. The Wyeth applicants contested that claims 23 and 24 were obvious in light of the '171 patent, but filed a terminal disclaimer confirming that it did not, and would not, seek an additional time period of patent protection beyond that afforded by the '171 Patent.

153. The Wyeth applicants also added claims 25 through 28, additional independent method of use claims. Claims 25 through 28 recited either a method of use "with diminished incidence of nausea" or for "eliminating the troughs and peaks of drug concentration in a patient's blood plasma." All are substantially similar to the method of use claims rejected by Examiner Hulina. Nonetheless, in the absence of the appropriate disclosures by Wyeth, Examiner Spear allowed claims 23 through 28.

154. On July 16, 2002, the '412 application issued as the '958 Patent. The '958 Patent contains six methods of use claims: claims 1-6. All related to either diminished incidences of nausea or eliminating the troughs and peaks in a patient's blood plasma. (Due to renumbering, proposed claims 23 and 24 issued as claims 1 and 2. Proposed claims 25 through 28 issued as claims 3 through 6.)

**(4) Wyeth Did Not Disclose the Previous
Examiner's Rejection in the '965
Application**

155. On September 12, 2001, the Wyeth applicants filed the '965 continuation-in-part application. The '965 application was again assigned to Examiner Spear.

156. The '965 application contained the same specification and claims as the '412 application (and corresponding '958 Patent). The Wyeth applicants canceled claims 2-22 and added new claims 23-34. Claim 23 recited a method of use claim for diminished incidences of nausea, and was substantially similar to rejected claim 9 of the '137 application:

23. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis which comprises administering orally to a patient in need thereof, an extended release formulation that provides a peak blood plasma level of venlafaxine of no more than 150 ng/ml, said formulation containing venlafaxine hydrochloride as the active ingredient.

157. Once again, the Wyeth applicants (a) never disclosed to Examiner Spear that a previous Examiner determined a claim substantially similar to claim 23 was unpatentable; (b) never disclosed that it had agreed to amend a substantially similar claim in order to avoid a rejection over the prior art disclosed by Wyeth's own Upton Patent; (c) never directed the examiner to the Upton Patent reference to extended release venlafaxine.

158. Examiner Spear allowed claim 23 and objected to claims 24-34. The Wyeth applicants later amended claims 24 and 25 to depend from allowed claim 23. Examiner Spear allowed the amended claims.

159. On June 11, 002, the '965 application issued as the '120 Patent. Due to renumbering, proposed claim 23 issued as claim 1:

1. A method for providing a therapeutic blood plasma

concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis which comprises administering orally to a patient in need thereof, an extended release formulation that provides a peak blood plasma level of venlafaxine of no more than 150 ng/ml, said formulation containing venlafaxine hydrochloride as the active ingredient.

160. All other claims depended on claim 1.

d. Wyeth Intentionally Failed to Disclose Material Information to the PTO

161. The prosecution history of the '137 Patent shows that Examiner Hulina judged the independent method of use claims (claims 9 and 10) unpatentable in view of the prior art taught by Wyeth's Upton Patent. Claims 9 and 10 became patentable only after Wyeth amended the claims to be dependent on a particular formulation of extended release venlafaxine at the insistence of Examiner Hulina.

162. Throughout the prosecution history of the method of use patents (including the '328 application, the '412 application, and the '629 application), Wyeth failed to (a) inform Examiner Spear that the Upton Patent identified the existence of an extended release formulation of venlafaxine that rendered their method of use claims unpatentable; and (b) disclose material information relating to Examiner Hulina's determination of unpatentability.

163. The Wyeth applicants had a duty to disclose all information material to patentability, including information that by itself renders the claims unpatentable. Instead, the Wyeth applicants failed to disclose to Examiner Spear: (a) the contrary findings of the earlier examiner on the identical claims; (b) the basis of the earlier examiner's contrary findings - that a prior art patent owned by Wyeth itself taught an extended release formulation of venlafaxine; (c) the fact that they had already agreed to narrow the scope of identical claims in order to avoid a rejection over Wyeth's own prior art patent - the Upton Patent; (d) the fact that only once they

had agreed to amend the claims to overcome the prior art reference, that Examiner Hulina found the claims patentable and issued a Notice of Allowability.

164. The information withheld by the Wyeth applicants was material. This information is of the type a reasonable examiner would want to know, as it directly impacts the patentability of the claims.

165. The Wyeth applicants withheld this material information and thereby breached their duty of disclosure to the PTO. They did so in order to avoid a decision that the independent method of use claims were unpatentable due to prior art.

166. The Wyeth applicants withheld this material information with intent to mislead and/or deceive the PTO. Intent to deceive the PTO can be inferred by refiling claims that had been previously rejected. Wyeth knowingly presented unpatentable and previously rejected claims to the examiner on multiple occasions without disclosing the fact of their previous rejection..

167. The Wyeth applicants failed to amend the independent method of use claims in accordance with Examiner Hulina's findings in the subsequent patent applications. The Wyeth applicants had multiple opportunities to amend the claims during prosecution of the method of use patents, and in fact did amend the claims several times. However, the Wyeth applicants never made the necessary amendments to overcome patent-defeating prior art on identically or substantially similar claims.

168. The Wyeth applicants had multiple opportunities to correct the record and bring the rejection of the claims based on the Upton Patent to the attention of Examiner Spear, yet failed to do so. The Wyeth applicants amended the claims several times in each subsequent application; Wyeth amended the specifications of two subsequent applications (the '328

application and the ‘629 application, which issued as the ‘171 patent) and amended the inventorship of the ‘629 application. Each filing presented an opportunity for Wyeth to correct the record, but it failed to do so.

169. Intent to deceive the PTO can be inferred by the numerous opportunities that Wyeth had to amend claims and specifications and/or bring the prior decision of unpatentability to Examiner Spears’ attention. Due to the high materiality of failure to disclose all the pertinent information during prosecution, Wyeth’s failure to disclose all pertinent information that was known to them during prosecution of the ‘171, ‘120, and ‘958 Patents can only be considered as intentional conduct to deceive the PTO.

170. But for this fraud on the PTO, no independent nausea or “troughs and peaks” method of use claims would have issued in the method of use patents. Wyeth’s fraud infects and renders invalid and/or unenforceable claims 20 through 25 of the ‘171 Patent and all of the claims of the ‘958 and ‘120 Patents.

E. Wyeth Engaged in Sham Litigation Against Thirteen Generic Manufacturers

171. Wyeth wrongfully listed all three of the fraudulently obtained method of use patents in the Orange Book.

172. At least 12 generic manufacturers sent Paragraph IV certifications to Wyeth, informing it that they intended to manufacture AB-rated generic equivalents to Effexor XR and claiming their products would not infringe Wyeth’s patents. In each and every instance, Wyeth sued the generic for infringement of the ‘171, ‘958, and the ‘120 Patents. Wyeth even sued a generic manufacturer Osmotica whose product was a tablet not a capsule like Effexor, not an AB-rated generic equivalent of Effexor XR, and could not possibly have infringed the ‘171, ‘958 and ‘120 Patents.

173. Wyeth knew that all three of its method of use patents were invalid and/or unenforceable, that the clinical evidence did not support its comparative statements between Effexor XR and instant release Effexor; that prior art existed for its patent claims; Wyeth also knew that it had no reasonable likelihood of succeeding on the merits of its dozen infringement lawsuits where sophisticated parties acquire detailed evidence about the circumstances of the acquisition of a patent.

174. Knowing that its method of use patents were invalid and unenforceable, Wyeth settled each and every infringement lawsuit before any court could issue a final decision as to whether its method of use patents were valid or enforceable.

1. Teva

175. On December 10, 2002, Teva Pharmaceuticals USA, Inc. (“Teva”) filed an ANDA seeking approval of a generic version of Effexor XR. Teva’s ANDA included a Paragraph IV certification that Wyeth’s method of use patents were invalid, unenforceable, and would not be infringed by its generic extended release venlafaxine capsules.

176. As the first ANDA applicant to submit a substantially complete ANDA, Teva was entitled to be the only non-authorized generic on the market for 180 days. When a generic version of a brand name drug is marketed, the branded manufacturer often begins to sell both the branded version and an “authorized” generic version, usually selling the same exact pills in different bottles. The branded company’s competing authorized generic can drastically reduce the first filed generic’s profits during its six month exclusivity window.

177. On March 24, 2003, Wyeth brought suit against Teva in the District of New Jersey, charging Teva with infringement of claims 20-25 of the ‘171 patent, claims 1, 2, 13, and 14 of the ‘120 Patent, and claims 1-6 of the ‘958 Patent. All are method of use claims for either

reducing the incidence of nausea or smoothing out the troughs and peaks in the blood serum.

Wyeth did not assert Teva infringed any of the formulation claims. Wyeth did not claim Teva infringed any other patents. The claim terms in dispute were: “extended release formulations,” “spheroid,” “with diminished incidence(s) of nausea and emesis,” and “encapsulated.”

178. Teva answered, denying the allegations and claiming that all the patents were invalid and not infringed. The case was closed per an order on January 20, 2006 after the parties filed under seal a Joint Settlement and Release Agreement on November 2, 2005.

179. As part of the settlement agreement, Wyeth gave Teva an exclusive license to sell a generic version of instant release Effexor before the original compound patent for venlafaxine expired. The Husbards Patent expired in June 2008; with Wyeth’s permission, Teva obtained FDA approval and began selling generic instant release venlafaxine in October 2006 - over a year and a half before it otherwise could have.

180. Wyeth also agreed to refrain from selling an authorized generic version of instant release Effexor until the Husbards Patent expired - giving Teva at least a year and a half of being the only instant release generic on the market.

181. Wyeth also gave Teva an exclusive license to sell a generic version of extended release Effexor XR for a fixed period of time. The license from Wyeth did not allow Teva to start selling a generic version of Effexor XR for approximately two years after the Husbards Patent expired in 2008. Teva began selling generic extended release venlafaxine capsules in June 2010.

182. Wyeth additionally agreed to refrain from selling an authorized generic version of Effexor XR during the fixed duration of Teva’s license.

183. Had Wyeth not fraudulently obtained the ‘171, ‘120, and ‘958 Patents, and/or not

listed those patents in the Orange Book, and/or not brought a sham infringement lawsuit based on these patents, Teva would have come to market in June 2008.

2. Impax

184. On April 5, 2006, Wyeth brought suit against Impax Laboratories, Inc. (“Impax”) in the District of Delaware for infringement of the claims 20-25 of the ‘171 Patent, claims 1-6 of the ‘958 Patent, and claims 1, 2, 13, and 14 of the ‘120 Patent.

185. Impax answered, denying the allegations and claiming that all the patents were invalid, not infringed, and unenforceable.

186. On May 13, 2008 an order entered at the joint request of the parties to have the court defer ruling on pending motions for summary judgment. The parties avoided a ruling on the merits.

187. The case was closed per a consent judgment on July 15, 2008, after the parties filed under seal a Joint Settlement and Release Agreement on June 9, 2008. Under the order, the parties purportedly stipulated that the patents were valid, enforceable, and infringed upon. Impax agreed not to enter the market until expiration of the ‘171 Patent, the ‘120 Patent, and the ‘958 Patent.

188. As part of the settlement, Wyeth granted Impax a license to market its generic version of Effexor XR on June 1, 2011, subject to earlier launch in limited circumstances, but in no event earlier than January 1, 2011.

3. Anchen

189. On April 12, 2006, Wyeth brought suit against Anchen Pharmaceuticals, Inc. (“Anchen”) in the Central District of California for infringement of the ‘171 Patent, the ‘120 Patent and the ‘958 patent. Anchen answered, denying the allegations, and claiming that all the

patents were invalid, not infringed, and unenforceable.

190. The case was closed per an order on November 3, 2008, after the parties filed under seal a Joint Settlement and Release Agreement on September 26, 2008. Under the order, the parties purportedly stipulated that the patents were valid, enforceable, and infringed. Anchen agreed not to enter the market until expiration of the ‘171 Patent, the ‘120 Patent, and the ‘958 Patent; however, the agreement provides a license to Anchen on undisclosed terms.

4. Lupin

191. On March 12, 2007, Wyeth brought suit against Lupin Ltd. (“Lupin”) in the District of Maryland for infringement of the claims 20-25 of the ‘171 Patent, claims 1-6 of the ‘958 Patent, and claims 1 and 2 of the ‘120 Patent. Lupin answered, denying the allegations and claiming that all the patents were invalid and not infringed.

192. The case was closed per an order on April 23, 2009, after the parties filed under seal a Joint Settlement and Release Motion on March 6, 2009. Under the order, the parties purportedly stipulated that the patents were both valid and infringed. Lupin agreed not to enter the market until expiration of the ‘171 Patent, the ‘120 Patent, and the ‘958 Patent; however, the agreement provides a license to Lupin on undisclosed terms.

5. Osmotica

193. On April 20, 2007, Wyeth brought suit against Osmotica Pharmaceuticals Corporation (“Osmotica”) in the Eastern District of North Carolina for infringement of “asserted claims,” which include claims 1-6 of the ‘958 Patent and claim 1 of the ‘120 patent. The parties disputed the term “extended release formulations.” Osmotica answered, denying the allegations and claiming that all the patents were invalid, non-infringed, and unenforceable.

194. Osmotica sought to market a tablet form of extended release venlafaxine.

Osmotica's NDA sought approval under the hybrid provisions of 505(b)(2) of the FDCA.

Osmotica's product, by definition, was not an AB-rated generic equivalent of Effexor XR.

195. The case was closed per an order on March 19, 2008 after the parties filed under seal a Joint Settlement and Release Agreement on March 17, 2008. Under the order, Osmotica agreed not to enter the market until expiration of the '171 Patent, the '120 Patent, and the '958 Patent; however, the agreement provides a license to Osmotica on undisclosed terms.

6. Sandoz

196. On June 22, 2007, Wyeth brought suit against Sandoz, Inc. ("Sandoz") in the Eastern District of North Carolina for direct infringement, active inducement of infringement, and contributory infringement of claims 20-25 of the '171 Patent, claims 1-6 of the '958 Patent, and claims 1, 2, 13, and 14 of the '120 Patent.

197. Sandoz answered, denying the allegations and claiming that all the patents were invalid, not infringed, and unenforceable.

198. According to a Status Report filed on February 2, 2011, the parties are currently working toward a resolution.

7. Mylan

199. On July 6, 2007, Wyeth brought suit against Mylan Pharmaceuticals Inc. ("Mylan") in the Northern District of West Virginia for direct infringement, active inducement of infringement, and contributory infringement of claims 20-25 of the '171 Patent, claims 1-6 of the '958 Patent, and claims 1, 2, 13, and 14 of the '120 Patent. Mylan answered, denying the allegations and claiming that all the patents were invalid and not infringed.

200. As part of its summary judgment briefing, Wyeth argued that any particular formulation of extended release venlafaxine hydrochloride was not novel - in direct

contradiction to its representations to the PTO in obtaining the patents.

201. On October 14, 2009 an order denied, in part, and granted, in part, Mylan's motions for summary judgment. Judge Keeley denied Mylan's motions regarding infringement and enablement, and granted Wyeth's motion regarding inventorship. Mylan's other defenses, including its invalidity defenses, remained unresolved.

202. The case was closed per a dismissal order on December 21, 2009, after the parties filed under seal a Joint Settlement and Release Motion on November 30, 2009. Under the order, Mylan agreed not to enter the market until expiration of the '171 Patent, the '120 Patent and the '958 Patent. However, the agreement provides a license to Mylan on undisclosed terms.

8. Biovail

203. On June 26, 2008, Wyeth brought suit against Biovail Corporation ("Biovail") in the District of Delaware for infringement of the '171 Patent, the '120 Patent and the '958 Patent. Biovail answered, denying the allegations, and claiming that all the patents were invalid and not infringed.

204. The case was closed per an order on March 19, 2010, after the parties filed under seal a Joint Motion to Enter Consent Judgment and to Enter Stipulated Order on November 12, 2009. Under the order, the parties purportedly stipulated that the patents were both valid and infringed. Biovail agreed not to enter the market until expiration of the '171 Patent, the '120 Patent and the '958 Patent. However, the agreement provides a license to Biovail on undisclosed terms.

9. Apotex

205. On August 18, 2008, Wyeth brought suit against Apotex Inc. and Apotex Corp. ("Apotex") in the Southern District of Florida for infringement of claims 2-20 of the '171 Patent,

claims 1-6 of the '958 Patent, and claims 1, 2, 13, and 14 of the '120 Patent.

206. Apotex answered, denying the allegations, and claiming that all the patents were invalid, not infringed and unenforceable for inequitable conduct.

207. The case was closed per an order on September 15, 2010, after the parties filed under seal a Joint Settlement and Release Agreement on August 11, 2010. Under the order, the parties purported to stipulate that the patents were valid, enforceable, and infringed. Apotex agreed not to enter the market until expiration of the '171 Patent, the '120 patent and the '958 Patent. However, the agreement provides a license to Apotex on undisclosed terms.

10. Torrent

208. On January 8, 2009, Wyeth brought suit against Torrent Pharmaceuticals Limited and Torrent Pharma Inc. ("Torrent") in the District of Delaware for infringement of the '171 Patent, the '120 Patent and the '958 Patent. Torrent answered, denying the allegations and claiming that all the patents were invalid and not infringed.

209. The case was closed per an order on June 30, 2010, after the parties filed under seal a Joint Settlement and Release Agreement on May 6, 2010. Under the order, the parties purported to stipulate that the patents were both valid and infringed and Torrent agreed not to enter the market until expiration of the '171 Patent, the '120 Patent and the '958 Patent. However, the agreement provides a license to Torrent on undisclosed terms.

11. Cadila

210. On April 9, 2009, Wyeth brought suit against Cadila Healthcare Limited and Zydus Pharmaceuticals (USA) ("Cadila") in the District of Delaware for infringement of the '171 Patent, the '120 Patent and the '958 Patent. Cadila answered, denying the allegations, and claiming that all the patents were invalid and not infringed.

211. The case was closed per an order on March 30, 2010 after the parties filed under seal a Joint Settlement and Release Agreement on January 28, 2010. Under the order, the parties purported to stipulate that the patents were valid and infringed, and Cadila agreed not to enter the market until expiration of the ‘171 Patent, the ‘120 Patent and the ‘958 Patent. However, the agreement provides a license to Cadila on undisclosed terms.

12. Aurobindo

212. On April 22, 2010, Wyeth brought suit against Aurobindo Pharma Limited (“Aurobindo”) in the District of New Jersey for the infringement of the ‘171 Patent, the ‘120 Patent and the ‘958 Patent. Aurobindo answered, denying the allegations, and claiming that all the patents were invalid and not infringed.

213. The case was closed per an order on January 6, 2011. The parties purported to stipulate that the patents were valid and infringed upon, and Aurobindo agreed not to enter the market until expiration of the ‘171 Patent, the ‘120 Patent and the ‘958 Patent. However, the agreement between Wyeth and Aurobindo provides a license to Aurobindo on undisclosed terms.

13. Orchid

214. On July 2, 2009, Wyeth brought suit against Organon Pharma Inc. and Orchid Chemicals and Pharmaceuticals (collectively, “Orchid”) in the District of New Jersey for the infringement of the ‘171 Patent, the ‘120 Patent and the ‘958 Patent. Orchid answered, denying the allegations, and claiming that all three patents were invalid, unenforceable, and not infringed.

215. A consent order of final judgment was entered on April 14, 2011. The parties purported to stipulate that the patents were valid and infringed, and Orchid agreed not to enter the market until expiration of the ‘171 Patent, the ‘120 Patent and the ‘958 Patent. However, the agreement between Wyeth and Orchid provides a license to Orchid on undisclosed terms.

F. Prior Allegations and Evidence of the Invalidity and Unenforceability of Wyeth's Method of Use Patents

216. In patent infringement litigation against generic manufacturers, allegations about validity or enforceability, or rulings on the merits against a patent holder, are the kind of procedural developments that taint the patent with an issue regarding its validity or enforceability.

217. Here, Wyeth asserted 12 different generic manufacturers infringed the method of use patents. Simply by filing suit, Wyeth kept each of the 12 generic versions of Effexor XR off the market for the shorter of two-and-a-half years or a decision on the merits. In answering Wyeth's claim of infringement, each of the generic companies claimed that the patents were invalid. Several of the generic companies also alleged the patents were unenforceable due to inequitable conduct. The validity and enforceability was to be actively litigated between Wyeth and the generic manufacturers.

218. However, Wyeth settled each and every Effexor XR infringement suit before each court could render an opinion on the validity or enforceability of Wyeth's patents. Wyeth orchestrated settlements with the potential competitors in order to bring an end to the litigation it started before a court could find the asserted method of use patents invalid or unenforceable.

219. Although Wyeth started a dozen infringement lawsuits against would-be competitors (who in turn alleged that the patents were invalid and/or unenforceable), no court has, yet, entered an order determining the invalidity or enforceability of the '171, '958, and '120 patents. The only court to issue a substantive decision on the merits denied Wyeth's motion for summary judgment regarding infringement but did not determine whether or not the patents themselves were valid and/or enforceable. In the rare instances where litigation with the generic manufacturers approached either a summary judgment decision addressing

invalidity/enforceability or a trial date, Wyeth settled with the potential competitors.

220. Wyeth has and is attempting to avoid liability for the anticompetitive effects of its fraudulent procurement of the method of use patents by bringing lawsuits it know it will lose and settling with the alleged infringing generic companies before the merits can be adjudicated. If the terms are favorable, generic manufacturers have a significant incentive to accept Wyeth's offer. However, End-payor purchasers are still harmed by Wyeth's anticompetitive scheme and sham litigation. Settlement by the parties to the infringement actions cannot preclude those harmed by the anticompetitive effects of Wyeth's wrongful actions (in both obtaining the patents and filing infringement suits) from seeking recovery for their damages.

MONOPOLY POWER AND MARKET DEFINITION

221. At all relevant times, Wyeth had monopoly power over Effexor XR and its generic equivalents because it had the power to maintain the price of Effexor XR at supracompetitive levels without losing substantial sales to other products prescribed and/or used for the same purposes as Effexor XR, with the exception of generic extended-release venlafaxine hydrochloride capsules.

222. A small but significant, non-transitory price increase by Wyeth for Effexor XR would not have caused a significant loss of sales to other products prescribed and/or used for the same purposes as Effexor XR, with the exception of generic extended-release venlafaxine hydrochloride capsules.

223. Effexor XR does not exhibit significant, positive cross-elasticity of demand with respect to price, with any product other than AB-rated generic versions of Effexor XR.

224. Patients respond differently to different psychotropic drugs, and selection of the proper drug for a patient by a doctor is not determined by price. Effexor XR is thus

differentiated from all products other than AB-rated generic versions of Effexor XR.

225. Wyeth needed to control only Effexor XR and its AB-rated generic equivalents, and no other products, in order to maintain the price of Effexor XR profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Effexor XR would render Defendant unable to profitably maintain its current prices of Effexor XR without losing substantial sales.

226. Wyeth also sold Effexor XR at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

227. Wyeth has had, and exercised, the power to exclude competition to Effexor XR.

228. Wyeth, at all relevant times, enjoyed high barriers to entry with respect to Effexor XR.

229. To the extent that Plaintiff is legally required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiff alleges that the relevant market is all extended release venlafaxine hydrochloride capsules - i.e., Effexor XR (in all its forms and dosage strengths) and AB-rated generic versions of extended release venlafaxine capsules. During the period relevant to this case, Defendant has been able to profitably maintain the price of Effexor XR well above competitive levels.

230. The relevant geographic market is the United States and its territories.

231. Wyeth's market share in the relevant market was 100% until June of 2010.

MARKET EFFECTS

232. Wyeth's acts and practices had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Effexor XR from generic competition. Wyeth's actions allowed it to maintain a monopoly and exclude competition in the market for

extended release venlafaxine capsules, *i.e.*, Effexor XR and its AB-rated generic equivalents, to the detriment of Plaintiffs and all other members of the End-Payor Class.

233. Wyeth's exclusionary conduct has delayed generic competition and unlawfully enabled it to sell Effexor XR without generic competition. But for Wyeth's illegal conduct, one or more generic competitors would have begun marketing AB-rated generic versions of Effexor XR much sooner than they actually were marketed, and, at all events, would have been on the market no later than June 14, 2008. By way of examples and not limitation: (a) if there had been no fraud upon the PTO, the '171, '958, and '120 Patents would not have issued, the patents would never have been listed in the Orange Book, and thus the patents would never have been the subject of infringement litigation that led to the 30-month Hatch-Waxman month stay; (b) if there had been no patents, there would have been no lawsuits, and with no lawsuits there would have been no settlements, all of which acted to further delay FDA approval and the timing of generic launch; (c) if the lawsuits had not been brought, the 30 month Hatch-Waxman stay would never have been triggered, no settlements would have been necessary, and FDA approval would have been forthcoming by June of 2008 with generic makers ready, willing, and able to launch at that time.

234. The generic manufacturers seeking to sell generic Effexor XR had extensive experience in the pharmaceutical industry, including in obtaining FDA approval for ANDAs, and in marketing generic pharmaceutical products.

235. Wyeth's illegal acts to delay the introduction into the U.S. marketplace of any generic version of Effexor XR caused Plaintiff and the Class to pay more than they would have paid for extended release venlafaxine capsules, absent Wyeth's illegal conduct.

236. Typically, generic versions of brand-name drugs are initially priced significantly

below the corresponding branded drug to which they are AB-rated. As a result, upon generic entry, End-Payor purchases of branded drugs are rapidly replaced by purchasers of AB-rated generic versions. As more generic manufacturers enter the market, prices for generic versions of a drug predictably decrease even further because of competition among the generic manufacturers, and, correspondingly, the brand name drug continues to lose even more market share to the generics. This price competition enables all End-payors of the drugs to purchase generic versions of a drug at a substantially lower price, and/or purchase the brand name drug at a reduced price.

237. If generic competitors had not been unlawfully prevented from entering the market earlier and competing with Wyeth, End-payors, such as Plaintiff and members of the Class, would have paid less for extended release venlafaxine capsules by (a) substituting purchases of less-expensive AB-rated generic Effexor XR for their purchases of more-expensive branded Effexor XR; (b) purchasing generic Effexor XR at lower prices sooner; and/or (c) paying less for purchases of brand name Effexor XR.

238. Thus, Wyeth's unlawful conduct deprived Plaintiff and the Class of the benefits of competition that the antitrust laws were designed to ensure.

ANTITRUST IMPACT

239. During the relevant period, Plaintiff and members of the Class purchased substantial amounts of Effexor XR from pharmacies and mail order houses. As a result of Wyeth's illegal conduct, members of the Class were compelled to pay, and did pay, artificially inflated prices for extended release venlafaxine prescriptions. Those prices were substantially greater than the prices that members of the Class would have paid absent the illegal conduct alleged herein, because: (a) the price of brand-name Effexor XR was artificially inflated by

Wyeth's illegal conduct; and/or (b) Class members were deprived of the opportunity to purchase lower-priced generic versions of Effexor XR sooner.

240. As a consequence, Plaintiff and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

CLASS ACTION ALLEGATIONS

241. Plaintiff brings this action on behalf of itself and as representative of a Class defined as follows:

All persons or entities throughout the United States and its territories who purchased and/or paid for Effexor XR or generic versions of Effexor XR during the period June 2008 to the present ("the Class Period") for consumption by themselves, their families, or their members, employees, insureds, participants or beneficiaries (the "Class"). For purposes of the Class definition, persons and entities "purchased" Effexor XR if they paid some or all of the purchase price.

Excluded from the Class are Defendant, its officers, subsidiaries and affiliates; all government entities (except for government-funded employee benefit plans); all persons or entities that purchased Effexor XR for purposes of resale, or directly from Defendant or its affiliates; and the judge in this case and any members of his/her immediate family.

242. Plaintiffs seek class certification pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure as to declaratory and equitable relief sought herein, and Rule 23(b)(3) as to the damages sought herein.

243. Although Plaintiff does not know the exact number of class members, it believes it to be, at a minimum, in the tens of thousands. During the year 2008, Wyeth received \$3,927,900,000 in net revenue from sale of Effexor XR. Thus, members of the Class are

numerous and joinder is impracticable. The Class members are identifiable, *inter alia*, from information and records that are required by law to be maintained by pharmacies, drugstores, pharmaceutical benefits managers, and managed care organizations.

244. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual members, in part because Defendants have acted and refused to act on grounds generally applicable to the entire Class, thereby making appropriate equitable, injunctive and declaratory relief with respect to the Class as a whole. Such conduct includes fraudulently obtaining the '171, '958, and '120 Patents; filing sham litigation; paying value to would-be competitors to settle patent infringement cases before a court could rule on the validity or infringement of Wyeth's patents; and converting the relevant market from one confronted with generic competition to one that is not for the sole purpose of monopolizing and attempting to monopolize the market for Effexor XR.

245. Questions of law and fact common to the Class include:

- (a) whether Defendant maintained or attempted to maintain monopoly power by delaying generic entry;
- (b) whether Defendant committed fraud on the PTO in obtaining any of the method of use patents for extended release venlafaxine capsules;
- (c) whether Wyeth improperly listed the method of use patents in the Orange Book;
- (d) whether direct proof of Defendant's monopoly power is available, and if available, whether it is sufficient to prove Defendant's monopoly power without the need to also define a relevant market;
- (e) to the extent a relevant market or markets must be defined, what that definition is or those definitions are;
- (f) whether the activities of Defendant as alleged herein have substantially affected interstate commerce;
- (g) whether Defendant's litigation asserting infringement of its patents

described herein was baseless;

- (h) whether Defendant engaged in sham litigation for the purpose of preventing competition;
- (i) whether Defendant intentionally and unlawfully excluded competitors and potential competitors from the market for Effexor XR and generic bio-equivalents to Effexor XR;
- (j) whether Plaintiff and members of the Class are entitled to declaratory, equitable and/or injunctive relief; and
- (k) whether Plaintiff and the Class have been damaged and the aggregate amount of damages.

246. Plaintiff's claims are typical of the members of the Class, in that Plaintiff purchased and/or paid for Effexor XR within the United States, including the Indirect Purchaser States, during the Class Period. Such purchases and payments were made for consumer consumption of Effexor XR. Plaintiff and all members of the Class were damaged by the same wrongful conduct of Defendant.

247. Plaintiff will fairly and adequately protect and represent the interests of the Class. The interests of Plaintiff are not antagonistic to those of the Class. In addition, Plaintiff is represented by counsel who are experienced and competent in the prosecution of complex class action antitrust litigation.

248. Class action treatment is a superior method for the fair and efficient adjudication of the controversy, in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress for claims that it might not be practicable to pursue individually, substantially outweigh any

difficulties that may arise in management of this class action.

249. Plaintiff knows of no difficulty to be encountered by litigating of this action that would preclude its maintenance as a class action.

FIRST CAUSE OF ACTION

FOR DECLARATORY AND INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT FOR DEFENDANTS' VIOLATIONS OF SECTION 2 OF THE SHERMAN ACT

250. Plaintiff repeats and realleges the preceding and subsequent paragraphs as though set forth herein.

251. Beginning in or about 1996, Wyeth knowingly and willfully engaged in a course of conduct designed to improperly obtain and extend its monopoly power in the manufacture and sale of extended release venlafaxine capsules. This course of conduct included, *inter alia*, the following acts: (a) commission of fraud upon the PTO by knowingly and willfully making false representations to the PTO and by withholding critical and material information from it; (b) knowingly listing baseless patents in the Orange Book; (c) the prosecution of baseless, sham patent litigation(s) against potential generic manufacturers; (d) offering things of value to potential competitors to dissuade them from engaging in lawful competition against Wyeth; (e) the intentional conversion of the relevant market from one confronting generic competition to one that is not; and (f) the intentional frustration of generic competition by effectively eliminating the ability for a generic therapeutic equivalent to be substituted for Effexor XR. The result of Wyeth's unlawful conduct has been to obtain and extend its monopoly.

252. Wyeth knowingly and intentionally engaged in sham litigation against manufacturers of AB-rated generic equivalents of Effexor XR. Wyeth repeatedly asserted that would-be competitors infringed its method of use patents, thereby automatically keeping each

potential generic competitors off the market for at least 30 months. Wyeth intentionally and deceptively alleged the generic manufacturers' products infringed its method of use patents. For each infringement suit, Wyeth knew at the time it filed that it had no realistic likelihood of success; that is, no realistic likelihood that a court would enforce the '171, '958, and '120 Patents against a generic company. Wyeth knew, therefore, that no reasonable pharmaceutical manufacturer would have believed it had a reasonable chance of succeeding on the merits of these infringement lawsuits. Wyeth filed these sham lawsuits for the purposes of using a governmental process (including the automatic 30-month stay of FDA approval) as an anticompetitive weapon to keep generics off the market.

253. Wyeth engaged in a series of sham lawsuits as part of a pattern or practice of successive filings undertaken for the purposes of harassing generic manufacturers, keeping generics off the market, and preserving its Effexor XR monopoly. Before a court could find the patents unenforceable, Wyeth settled each lawsuit and negotiated deals with the generic companies that kept the first generic off the market until June 2010, and the rest off the market until June 2011.

254. Wyeth engaged in three distinct *Walker Process* frauds:

(a) Wyeth obtained method of use claims for extended release venlafaxine by fraudulently claiming clinical data showed Effexor XR reduced the incidence of nausea and vomiting associated with instant release Effexor. Wyeth knew that its clinical data did not show a decreased incidence of nausea. Wyeth knew that this information would be material to the patent examiner but Wyeth intentionally withheld it in order to defraud the patent examiner into issuing patents that included method of use claims for the reduction in the incidence of vomiting.

(b) Wyeth obtained method of use claims for extended release venlafaxine by

failing to reveal that its own Upton Patent disclosed extended release venlafaxine and by failing to disclose that a previous patent examiner had found all method of use claims unpatentable in light of the Upton Patent. Wyeth knew that both the Upton Patent and the previous examiner's rejection of the method of use claims in light of the Upton Patent would be material to the later patent examiner. Wyeth intentionally withheld the Upton Patent and the related examiner's rejection in order to defraud the later patent examiner into issuing patents that included method of use claims.

(c) Wyeth fraudulently claimed that an extended release version of Effexor was unexpected, despite knowing the Upton Patent and the '589 PCT application previously disclosed extended release versions of Effexor. Wyeth intentionally failed to inform the examiner about the prior disclosures of extended release venlafaxine and further failed to correct its fraudulent representation that an extended release version of venlafaxine was surprising in order to defraud the patent examiner into issuing patents that pertained to Effexor XR.

255. Wyeth intentionally and wrongfully created and maintained a monopoly power in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

256. Plaintiff and the other members of the Class have been injured in their business or property by reason of Wyeth's antitrust violations alleged in this Count. Their injury consists of being deprived of the ability to purchase less expensive, generic versions of Effexor XR, and paying higher prices for such products than they would have paid in the absence of the antitrust violations. The injury to Plaintiff and the Class is the type of injury antitrust laws were designed to prevent, and the injury flows from Wyeth's unlawful conduct.

257. Plaintiff and the Class, pursuant to Rule 57 of the Federal Rules of Civil Procedure and 18 U.S.C. § 2201(a), hereby seek a declaratory judgment that Wyeth's conduct in

seeking to prevent competition as described herein violates Section 2 of the Sherman Act.

258. Plaintiff and the Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anti-competitive market effects caused by the unlawful conduct of Wyeth and other relief so as to assure that similar anti-competitive conduct does not occur in the future.

SECOND CAUSE OF ACTION

FOR COMPENSATORY AND MULTIPLE DAMAGES UNDER THE ANTITRUST AND/OR CONSUMER PROTECTION STATUTES OF THE INDIRECT PURCHASER STATES

259. Plaintiff repeats and realleges the preceding and subsequent paragraphs as though set forth herein.

260. Defendant's conduct described herein constitutes unlawful acts of monopolization and attempts to monopolize, as well as prohibited practices and unconscionable conduct under the antitrust and/or unfair and deceptive trade practices acts of the Indirect Purchaser States, as follows:

a. Arizona: The aforementioned practices by Defendant were and are in violation of the Arizona Uniform State Antitrust Act, Ariz. Rev. Stat. §§ 44-1401, *et seq.*, the Arizona Consumer Fraud Act, Ariz. Rev. Stat §§ 44-1521, *et seq.*, and/or the Constitution of the State of Arizona, Article 14, §15;

b. California: The aforementioned practices by Defendant were and are in violation of the Cartwright Act, Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and/or the California Unfair Competition Act, Cal. Bus. & Prof. Code §§ 17200, *et seq.*;

c. District of Columbia: The aforementioned practices by Defendant were and are in violation of the District of Columbia Antitrust Act, D.C. Code §§ 28-4501, *et seq.*;

d. Florida: The aforementioned practices by Defendant were and are in violation of the Florida Antitrust Act, Fla. Stat. Ann. §§ 542.15, *et seq.*, and/or the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. §§ 501.201, *et seq.*;

e. Hawaii: The aforementioned practices by Defendant were and are in violation of Hawaii Revised Statutes §§ 480-2, 480-3, and 480-4.

f. Iowa: The aforementioned practices by Defendant were and are in violation of the Iowa Competition Law, Iowa Code §§ 553.4, 553.5 (1997);

g. Kansas: The aforementioned practices by Defendant were and are in violation of the Kansas Monopolies and Unfair Trade Act, Kan. Stat. Ann. §§ 50-101, *et seq.*, and/or the Kansas Consumer Protection Act, Kan. Stat. Ann §§ 50-623, *et seq.*;

h. Kentucky: The aforementioned practices by Defendant were and are in violation of the Kentucky Consumer Protection Act, Ky. Rev. Stat. Ann. §§ 367.110, *et seq.*, and/or the Kentucky Unfair Trade Practices Act, Ky. Rev. Stat. Ann §§ 365.020, *et seq.*;

i. Maine: The aforementioned practices by Defendant were and are in violation of the Maine Monopolies and Profiteering Statute, Me. Rev. Stat. Ann. tit. 10, §§ 1101, *et seq.*, and/or the Maine Unfair Trade Practices Act, Me. Rev. Stat. Ann. tit. 5, §§ 205-A, *et seq.*;

j. Massachusetts: The aforementioned practices by Defendant were and are in violation of the Massachusetts Antitrust Act, Mass. Gen. Laws, ch. 93, and/or the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93A, in that the actions and transactions alleged herein occurred primarily and substantially within Massachusetts, with thousands of End-payors paying substantially higher prices for Effexor XR;

k. Michigan: The aforementioned practices by Defendant were and are in

violation of the Michigan Antitrust Reform Act, Mich. Comp. Laws §§445.771, *et seq.*, and/or the Michigan Consumer Protection Act, §§ 445.901, *et seq.*;

l. Minnesota: The aforementioned practices by Defendant were and are in violation of the Minnesota Antitrust Law of 1971, Minn. Stat. §§ 325D.49, *et seq.*, and/or the Minnesota Consumer Fraud Act, Minn. Stat §§ 325F.67, *et seq.*;

m. Mississippi: The aforementioned practices by Defendant were and are in violation of the Mississippi antitrust statute, Miss. Code Ann. §§75-21-1 *et seq.*, in that Defendant accomplished its monopolistic goals in part through transactions lying wholly within the state, with thousands of Mississippi End-payors paying substantially higher retail prices for Effexor XR at Mississippi pharmacies;

n. Nebraska: The aforementioned practices by Defendant were and are in violation of the Nebraska Consumer Protection Act, Neb. Rev. Stat. § 59-1601, *et seq.*;

o. Nevada: The aforementioned practices by Defendant were and are in violation of the Nevada Unfair Trade Practices Act, Nev. Rev. Stat. §§ 598A.010, *et seq.*, and/or the Nevada Deceptive Trade Practices Act, Nev. Rev. Stat. §§ 598.0903, *et seq.*, in that thousands of sales of Effexor XR took place at Nevada pharmacies, purchased by Nevada End-payors at supracompetitive prices caused by Defendant's conduct;

p. New Mexico: The aforementioned practices by Defendant were and are in violation of the New Mexico Antitrust Act, N.M. Stat. Ann. §§ 57-1-1, *et seq.*, and/or the New Mexico Unfair Practices Act, N.M. Stat. Ann. §§ 57-12-1, *et seq.*;

q. New York: The aforementioned practices by Defendant were and are in violation of the Donnelly Act, N.Y. Gen. Bus. Law §§ 340, *et seq.*, and/or the New York Deceptive Acts and Practices Act, N.Y. Gen. Bus. Law §§ 349, *et seq.*, and, to the extent New

York law so requires, Plaintiff hereby forgoes any minimum or punitive damages in order to preserve the right of New York Class members to recover by way of a class action;

r. North Carolina: The aforementioned practices by Defendant were and are in violation of North Carolina's antitrust and unfair competition law, N.C. Gen. Stat. §§ 75-1, *et seq.*;

s. North Dakota: The aforementioned practices by Defendant were and are in violation of the North Dakota Antitrust Act, N.D. Cent. Code §§ 51-08.1-01, *et seq.*, and/or the North Dakota Consumer Fraud Act, N.D. Cent. Code §§ 51-15-01, *et seq.*;

t. South Dakota: The aforementioned practices of Defendant were and are in violation of South Dakota's antitrust law, S.D. Codified Laws §§ 37-1-3, *et seq.*, and/or deceptive trade practices and consumer protection law, S.D. Codified Laws §§ 37-24-1, *et seq.*;

u. Tennessee: The aforementioned practices of Defendant were and are in violation of the Tennessee Trade Practices Act, Tenn. Code Ann. §§ 47-25-101, *et seq.*, and/or the Consumer Protection Act, Tenn. Code Ann. §§ 47-18-101, *et seq.*, in that the actions and transactions alleged herein substantially affected Tennessee, with thousands of End-payors in Tennessee paying substantially higher prices for Effexor XR at Tennessee pharmacies;

v. Utah: The aforementioned practices of Defendant were and are in violation of the Utah Trade Practices Act, Utah Code Ann. §§ 13-5-1, *et seq.*, the Utah Consumer Sales Practices Act, Utah Code Ann. §§ 13-11-1, *et seq.*, and/or Utah Code Ann. § 76-10-919;

w. Vermont: The aforementioned practices of Defendant were and are in violation of the Vermont Consumer Fraud Act, Vt. Stat. Ann. tit. 9, §§ 2451, *et seq.*;

x. West Virginia: The aforementioned practices by Defendant were and are

in violation of the West Virginia Antitrust Act, W.Va. Code §§ 47-18-1, *et seq.*, and/or the West Virginia Consumer Credit and Protection Act, W. Va. Code §§ 46A-6-101, *et seq.*; and

y. Wisconsin: The aforementioned practices by Defendant were and are in violation of the Wisconsin Antitrust Act, Wis. Stat. §§ 133.01, *et seq.*, and the Wisconsin Unfair Trade Practices Act, Wis. Stat. §§ 100.20, *et seq.*, in that the actions and transactions alleged herein substantially affected the people of Wisconsin, with thousands of End-payors in Wisconsin paying substantially higher prices for Effexor XR at Wisconsin pharmacies;

261. Defendant intended by its conduct to cause, and did cause, pharmacies in every state to charge higher prices for Effexor XR as a result of the lack of competition by AB-rated generic versions of Effexor XR, including transactions that occurred purely intrastate. Sales of Effexor XR at supracompetitive prices did occur in each state and the effects of the anticompetitive conduct were experienced in every state.

262. As a result of the conduct described above, Plaintiff and the Class have sustained and will continue to sustain substantial losses and damage to their businesses and property in the form of, *inter alia*, being deprived of the ability to purchase less expensive, generic versions of Effexor XR, and paying prices for such products that were higher than they would have been but for Defendant's improper actions. The full amount of such damages are presently unknown and will be determined after discovery and upon proof at trial.

263. Plaintiff and the Class seek damages, multiple damages, treble damages, punitive damages, and/or other damages as permitted by state law, for their injuries caused by these violations pursuant to these statutes.

THIRD CAUSE OF ACTION

FOR INJUNCTIVE AND DECLARATORY RELIEF UNDER THE ANTITRUST AND/OR CONSUMER PROTECTION STATUTES OF THE INDIRECT PURCHASER STATES

264. Plaintiff repeats and realleges the preceding and subsequent paragraphs as though set forth herein.

265. Defendant's conduct described herein constitutes unlawful acts of monopolization and attempts to monopolize, as well as prohibited practices and unconscionable conduct under the antitrust and/or unfair and deceptive trade practices acts of the Indirect Purchaser States, as stated more specifically in Count II above.

266. Plaintiff and the other members of the Class have been injured in their business or property by reason of Defendant's antitrust violations alleged in this Count. Their injury consists of being deprived of the ability to purchase less expensive, generic versions of Effexor XR, and paying higher prices for Effexor XR and generic versions of Effexor XR than they would have paid but for Defendant's improper actions. The injury to Plaintiff and the Class is the type of injury antitrust laws were designed to prevent, and the injury flows from Defendant's unlawful conduct.

267. Plaintiff and the Class, pursuant to laws of the Indirect Purchaser States, hereby seek a declaratory judgment that Wyeth's conduct in seeking to prevent competition through the scheme set forth herein is unlawful. Plaintiff and the Class further seek equitable and injunctive relief pursuant to the laws of the Indirect Purchaser States to correct for the anti-competitive market effects and other harms to purchasers caused by the unlawful conduct of Defendant, and other relief so as to assure that similar conduct does not occur in the future.

FOURTH CAUSE OF ACTION

FOR RESTITUTION, DISGORGEMENT AND CONSTRUCTIVE TRUST FOR UNJUST ENRICHMENT BY DEFENDANTS NATIONWIDE CLASS

268. Plaintiff repeats and realleges the preceding and subsequent paragraphs as though set forth herein.

269. As a result of their unlawful conduct described above, Defendant has been and will continue to be unjustly enriched. Specifically, Defendant has been unjustly enriched, to the detriment of Plaintiff and the Nationwide Class by the receipt of, at a minimum, unlawfully inflated prices and/or illegal monopoly profits on their sale of Effexor XR.

270. Defendant has benefitted from its unlawful acts and it would be inequitable for Defendant to be permitted to retain any of its ill-gotten gains resulting from the overpayments for Effexor XR made by Plaintiff and the Nationwide Class.

271. Plaintiff and members of the Nationwide Class are entitled to the amount of Defendant's ill-gotten gains resulting from Defendant's unlawful, unjust and inequitable conduct. Plaintiff and the Nationwide Class are entitled to the establishment of a constructive trust consisting of all ill-gotten gains from which Plaintiff and the Nationwide Class members may make claims on a *pro rata* basis.

WHEREFORE, Plaintiff prays that:

(a) the Court determine that this action may be maintained as a class action pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure with respect to Plaintiff's claims for declaratory, equitable and injunctive relief, and Rule 23(b)(3) of the Federal Rules of Civil Procedure with respect to the claims for damages; and declare Plaintiff as the representative of the Class;

(b) the conduct alleged herein be declared, adjudged and decreed to be in violation of Section 2 of the Sherman Act, of the statutes of the Indirect Purchaser States set forth above, and the common law of unjust enrichment nationwide;

(c) Plaintiff and each member of the Class be awarded damages and, where applicable, treble, multiple, punitive and/or other damages, according to the laws of the Indirect Purchaser States, including interest;

(d) Plaintiff and each member of the Class recover the amounts by which Defendant has been unjustly enriched;

(e) Defendant be enjoined from continuing the illegal activities alleged herein;

(f) Plaintiff and the Class recover their costs of suit, including reasonable attorneys' fees and expenses as provided by law;

(g) Plaintiff and the Class be granted such other and further as the Court deems just and necessary.

JURY DEMANDED

Plaintiffs demand a trial by jury, pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, of all issues so triable.

Dated: September 28, 2011



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